

NOTE: All systems and products should be considered as investigational-use only in the context of the NIH BRAIN or NIH SPARC Initiative.

VERCISE™ DEEP BRAIN STIMULATION SYSTEM

Description: 16-channel rechargeable implantable pulse generator. Each of the 16 current controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The size is 22 cc including the header.

Specifications:

Parameter	Range
Amplitude ^a	0.1 – 20 mA
Rate ^b	2-255 Hz
Pulse Width	10-450 μ s
Cycle (On/Off)	1s – 90 min
Stim Ramp ON	1 – 10 s
Independent Areas of Stim (4 Programs with 4 Areas per Program)	16

- a) The programmable coverage for each individual contact is limited to 12.7mA. A programming interlock is enforced to limit the total output current to 0mA or less per coverage area. For example, a maximum current output of 12.7mA on one contact would limit the total summed current output on the remaining contacts to 7.3mA within one coverage area.
- b) The rate is limited to 255Hz for a given area.



VERCISE™ PC DEEP BRAIN STIMULATION SYSTEM

Description: Similar to Vercise DBS rechargeable system in terms of stimulation capabilities but uses a primary cell battery and has a different form factor (33cc including the header). Includes new externals and software for support of the Directional 8 contact segmented DBS lead.



VERCISE™ GEVIA DEEP BRAIN STIMULATION SYSTEM

Description: Similar to Vercise PC DBS system in terms of capabilities, externals, and directional lead support, but with the following changes:

- Uses a rechargeable battery.
- Has a smaller form factor (19.8 cc including the header).
- Includes an MRI mode designed for MR scans under specific conditions.

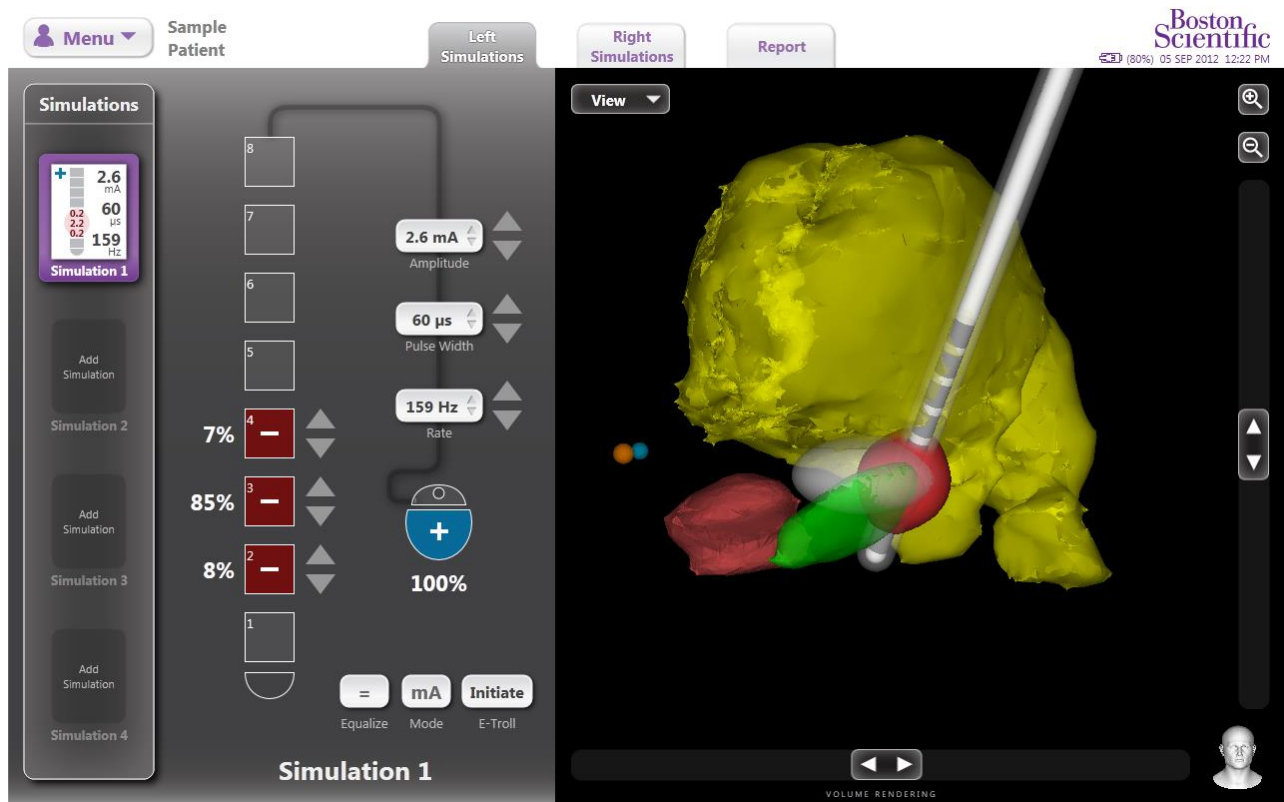


GUIDE™ DBS SOFTWARE

Description: GUIDE™ DBS Software (GUIDE DBS) is a simulation system that allows the clinician to plan the programming of a patient with a Boston Scientific Deep Brain Stimulation (DBS) System. GUIDE DBS provides:

- A view of the Lead(s) relative to the deep brain structures associated with treatment
- The tools for simulating neuron response to stimulation
- A visual model of the stimulation field in the context of an anatomical atlas.

Using GUIDE DBS, one can determine a starting point for the monopolar review that may reduce programming time.

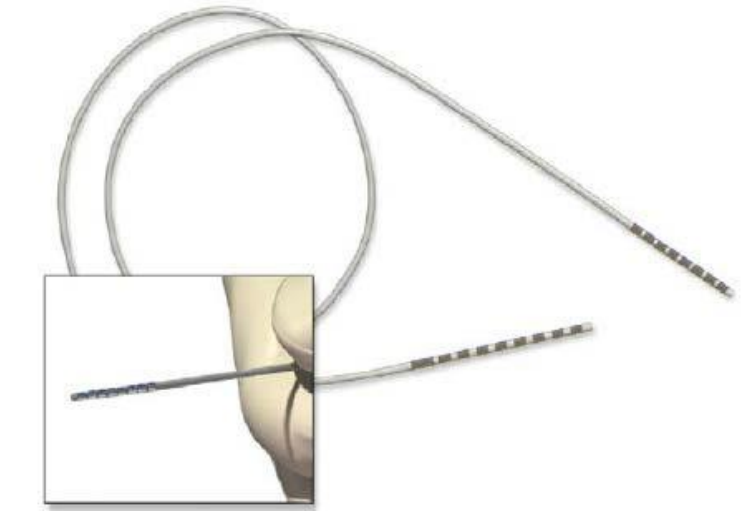


8-CONTACT DEEP BRAIN STIMULATION LEAD

Description: The DBS Lead consists of 8 cylindrical contacts. The outer diameter of the DBS Lead and contacts is 1.3 mm and is compatible with existing commercially available DBS implantation tools. The DBS Lead can be implanted and attached to the stimulator for both unilateral stimulation (on either the left or right side) and bilateral stimulation.

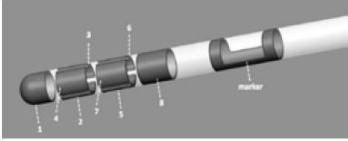
Specifications:

Feature	Description
Number of contacts	8
Contact Length	1.5mm
Contact spacing (center to center)	2.0mm
Contact span	15.5mm
Distal contact to tip	<1.3mm
Diameter	1.3mm
Overall Length	30cm, 45cm
Outer Jacket tubing (insulation)	Polyurethane
Contact Material	Platinum/Iridium



DIRECTIONAL 8 CONTACT SEGMENTED DEEP BRAIN STIMULATION LEAD

Description: Eight-contact segmented lead with current steering.

	Feature	Specification
	Tip Length	1.5 mm
	Contact Length	1.5 mm
	Contact Spacing (axial)	0.5 mm
	Lead Diameter	1.3 mm
	Overall Length	30 cm or 45 cm
	Outer Tubing Material	Polyurethane
	Contact Material	Platinum/Iridium



PRECISION WAVEWRITER™ SPINAL CORD STIMULATOR SYSTEM

Description: Latest generation 32-channel rechargeable implantable pulse generator (IPG). Each of the 32 current-controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The IPG size is 21.2 cc including the header. Various features allow unique electrode configuration and timing stimulation patterns. For example:

- Up to 4 areas activated simultaneously with different electrode configurations and independent stimulation parameters.
- Up to 16 independent programs
- Up to 4 schedules combining up to 12 programs in sequences with resolution from seconds to days per program.
- MicroBurst3D: a burst waveform with increased resolution in the 0 to 1 second range, within and between packets of stimulation.
- Unique fields to selectively activate dorsal column or dorsal horn neural elements.

Programmable Parameters

Parameter	Range
Amplitude	0-25.5mA
Rate	2-1200Hz ^a
Pulse Width	20-1000µs ^b
Cycle ON	0s-90min
Cycle OFF	0s-90min
Ramp UP	1-10s or OFF
Programmable Contacts	32 + IPG Case (Anode/Cathode/OFF)
Independent Areas of Stimulation per Program	4
Available Programs	16
Available Schedules	4
Available Programmable Tabs per Schedule	12
Program or Wait Period Duration within a Schedule	10 secs – 7 days

- a) Stimulation frequencies displayed are representative of only a single area being used in stimulation. When more than one area is used, the frequency of stimulation in an area may vary to accommodate pulses in other areas and may be less than the displayed frequency on the Clinician Programmer.
- b) Amplitude x Width ≤12.7µC for all leads other than the 4x8 Surgical lead; Amplitude X Width ≤ 9.1µC for the 4x8 surgical lead.



PRECISION SPECTRA™ SPINAL CORD STIMULATOR SYSTEM

Description: 32-channel rechargeable implantable pulse generator. Each of the 32 current-controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The size is 21.2 cc including the header.

Specifications:

Parameter	Range
Amplitude	0-25.5mA
Rate	2-1200Hz ^a
Pulse Width	20-1000µs ^b
Cycle ON	0s-90min
Cycle OFF	0s-90min
Ramp Up	1-10s or OFF
Programmable Contacts	32 + IPG case (Anode/Cathode / OFF)
Independent Areas of Stimulation per Program	4
Available Programs	16

- a) Only one Area is available if the rate is >130pps
- b) Amplitude x Width ≤12.7µC for all leads other than the 4x8 Surgical lead; Amplitude X Width ≤9.1µC for the 4x8 Surgical Lead

EXHIBIT C – BOSTON SCIENTIFIC PRODUCTS AVAILABLE FOR NIH BRAIN
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PRECISION NOVI™ SPINAL CORD STIMULATOR SYSTEM

Description: 16 channels of multiple independent current control utilizing a primary cell battery and a different form factor (33cc including the header).

Specifications:

Parameter	Range
Amplitude	0-25.5mA
Rate	2-1200Hz ^a
Pulse Width	20-1000μs ^b
Cycle ON	0s-90min
Cycle OFF	0s-90min
Ramp Up	1-10s or OFF
Programmable Contacts	16 + IPG case (Anode/Cathode/Off)
Independent Areas of Stimulation per Program	4
Available Programs	16

a) Only one Area is available if the rate is >130pps

b) Amplitude x Width ≤12.7μC for all leads other than the 4x8 Surgical lead; Amplitude X Width <9.1μC for the 4x8 Surgical Lead



PRECISION™ MONTAGE™ MRI SPINAL CORD STIMULATOR SYSTEM

Description: Similar to Precision NOVI specifications but with additional MRI capabilities.

PERCUTANEOUS SPINAL CORD STIMULATOR LEADS

Description: Various 1x8 contact electrode leads with 3 different electrode spacing configuration and 1x16 electrode contacts percutaneous linear lead configuration.

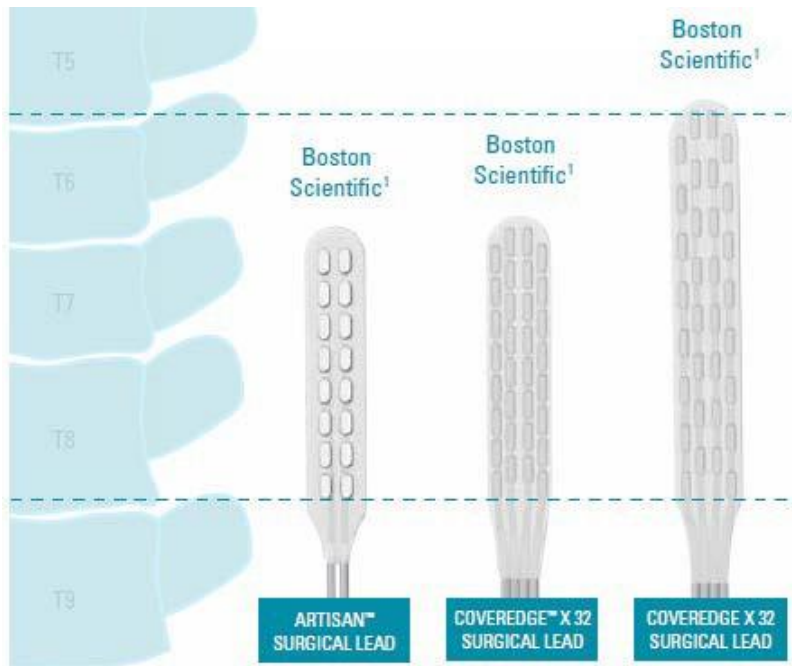
Additional information can be found at: http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91078744-07_Rev_A_Perc_Leads_DFU_Entrada2_WW_Whisper_en_US_S.pdf



SURGICAL PADDLE SPINAL CORD STIMULATOR LEADS

Description: 4x8 and 2x8 surgical paddle lead configurations are available.

Additional information can be found at: http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91078747-08_Rev_A_Surgical_Leads_DFU_WW_Whisper_en_US_S.pdf



Accessories such as connectors and adapters for connection to other manufacturers' leads:

M8 Connector: allows connection to selected Medtronic leads to a Boston Scientific pulse generator

http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893429-09RevA_Precision_M8_Adapter_DFU_en-US_S.pdf

S8 Connector: allows connection to selected St Jude leads to a Boston Scientific pulse generator

http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893896-09_RevA_Precision_S8_Adapter_DFU_en-USA_S.pdf

OMG connector: allows connection to selected Medtronic and St Jude leads to a Boston Scientific external trial stimulator during a trial evaluation period

http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91171773-01_RevA_Precision_Spectra_OMG_DFU_en-US_S.pdf

Additional information for Spinal Cord Stimulator products can be found at:

<http://www.bostonscientific.com/manuals/manuals/landing-page/US-english.html>