# **Proclaim™ SCS System**



### SUPERIOR PAIN RELIEF<sup>1,2</sup>—WITHOUT DISRUPTION

Offer your patients pain relief in an innovative system, featuring BurstDR<sup>TM</sup> stimulation and providing therapy without disruption: no external wires, wands or recharging. Patients control the device with an intuitive, familiar interface, with wireless therapy upgrades upon approval.

The Proclaim™ Elite spinal cord stimulation (SCS) system offers:

- A new, proven form of neurostimulation called BurstDR stimulation, exclusively from St. Jude Medical, for superior pain relief as compared to tonic stimulation.
- Invisible Therapy<sup>™</sup> for a better patient experience
- Recharge-free and MR Conditional device for convenience
- Low-profile device design for patient comfort<sup>3</sup>

### NOW WITH BURSTDR™ STIMULATION

BurstDR stimulation has been proven in multiple studies from around the world to deliver superior pain relief over tonic stimulation.<sup>1,2</sup> The revolutionary technology works by emulating natural firing patterns in the brain<sup>4</sup> and is believed to modulate both the sensory and emotional pathways—that may give patients relief from their painful sensations and their conscious attention to pain.<sup>5,6</sup>

#### A BETTER PATIENT EXPERIENCE WITH INVISIBLE THERAPY™

The Proclaim Elite SCS system, along with BurstDR stimulation, offers your patients the advantages of Invisible Therapy<sup>TM</sup>, allowing them to focus on their lives instead of their pain.

Invisible Therapy features:

- A recharge-free device
- Reduced or no paresthesia<sup>1,2</sup>
- Familiar, wireless Apple mobile digital devices
- Full-body MRI capability

For scan details of our current neuromodulation devices, refer to the <u>resources for</u> <u>radiology professionals</u>.

#### MOVE MORE PATIENTS FROM PAIN TO RELIEF

The Proclaim™ Elite recharge-free SCS system is part of our spinal cord stimulation (SCS) portfolio. Our vision is to transform the management of chronic pain by offering advanced technologies designed to improve patient outcomes and experience to bring the benefits of SCS to more patients. Read more about the <u>portfolio</u> and our approach to <u>chronic pain management</u>.

## **IPG Specifications**

The Proclaim™ IPGs have the following physical specifications.

Table 3. IPG specifications

Model			MRI Status	Upgradeable Features, Burst Capable	Compatible Header
	3660	3662	MR Conditional	Yes	No
	3661	3663	MR Unsafe	Yes	Yes
	3665	3667	MR Unsafe	No	No
Height	5.55 cm (2.19 in)	6.68 cm (2.63 in)			
Length	4.95 cm (1.95 in)	5.02 cm (1.98 in)		Z-10	
Thickness	1.34 cm (0.53 in)	1.35 cm (0.53 in)	1 /		
Weight	48.9 g (1.7 oz)	58.3 g (2.1 oz)	1 /		3
Volume	30.4 cm <sup>3</sup> (1.9 in <sup>3</sup> )	38.6 cm <sup>3</sup> (2.4 in <sup>3</sup> )		0	
Power source	Carbon monofluoride/silver vanadium oxide cell				
Connector strength	10 N (Models 3660, 3662, 3665, 3667) 5 N (Models 3661, 3663)				<i>y</i>
Program storage capacity	15 programs with	8 stim sets each			

Table 4. Operating parameters for the IPG

Parameter	Tonic Range	Tonic Steps	Burst Range*	Burst Steps*
Pulse width	20–1000 μs	10 μs (20–500 μs range)	50–1000 μs	50 μs
		50 μs (500–1000 μs range)		
Frequency	2-200 Hz	2 Hz	<del>5</del>	₩ <del></del>
	200-500 Hz	10 Hz	<del></del>	Ser.
	500-1200 Hz	20 Hz	=	8
Burst rate frequency	<del></del>	-	10–60 Hz	10 Hz
Intraburst	W <u></u>	<u></u>	250-500 Hz	10 Hz
frequency			500-1000 Hz	20 Hz
Amplitude	0-25.5 mA	0.1-1.0 mA	0.10.75 4	0.05-0.50 mA
	0-12.75 mA	0.05-0.50 mA	- 0−12.75 mA	

NOTE: Columns with \* represent operating parameters for BurstDR $^{\text{TM}}$  stimulation programs on IPGs capable of BurstDR stimulation mode.

NOTE: For each tonic program, you have the option to select the amplitude range. For information on setting the amplitude range, see the clinician's programming manual for this system.

NOTE: The number of stim sets in use for a tonic program governs the maximum frequency (1200/number of stim sets).

NOTE: The maximum current depends on the impedance, frequency, and pulse width settings.

#### REFERENCES

- \*BurstDR™ neurostimulation, exclusively from St. Jude Medical, is also referred to as Burst stimulation in clinical literature.
- \*\*Refer to the Instructions for Use for full details on the Proclaim™ Elite IPG MR Conditional scan parameters. Apple is a trademark of Apple, Inc.
- 1. St. Jude Medical. (2016). St. Jude Medical™ Proclaim™ Neurostimulation System Clinician's Manual. Plano, TX.
- 2. St. Jude Medical. (2016). St. Jude Medical™ Prodigy™ Neurostimulation System Programming and Reference Manual. Plano, TX.
- 3. St. Jude Medical. Engineering Report 90191496.
- 4. De Ridder, D., Vanneste, S., Plazier, M., & Vancamp, T. (2015). Mimicking the brain: Evaluation of St. Jude Medical's Prodigy Chronic Pain System with Burst Technology. *Expert Review of Medical Devices*, *12*(2), 143–150. http://dx.doi.org/10.1586/17434440.2015.985652
- 5. Van Havenbergh, T., Vancamp, T., Van Looy, P., Vanneste, S., & De Ridder, D. (2014.) Spinal cord stimulation for the treatment of chronic back pain patients: 500-hz vs. 1000-hz burst stimulation. *Neuromodulation*, *18*(1), 9-12. <a href="http://dx.doi.org/10.1111/ner.12252">http://dx.doi.org/10.1111/ner.12252</a>
- 6. Schu, S., Slotty, P.J., Bara, G., von Knop, M., Edgar, D., & Vesper, J. (2014). A prospective, randomized, double-blind, placebo-controlled study to examine the effectiveness of burst spinal cord stimulation patterns for the treatment of failed back surgery syndrome. *Neuromodulation*, 17(5), 443-450. <a href="https://dx.doi.org/10.1111/ner.12197">https://dx.doi.org/10.1111/ner.12197</a>