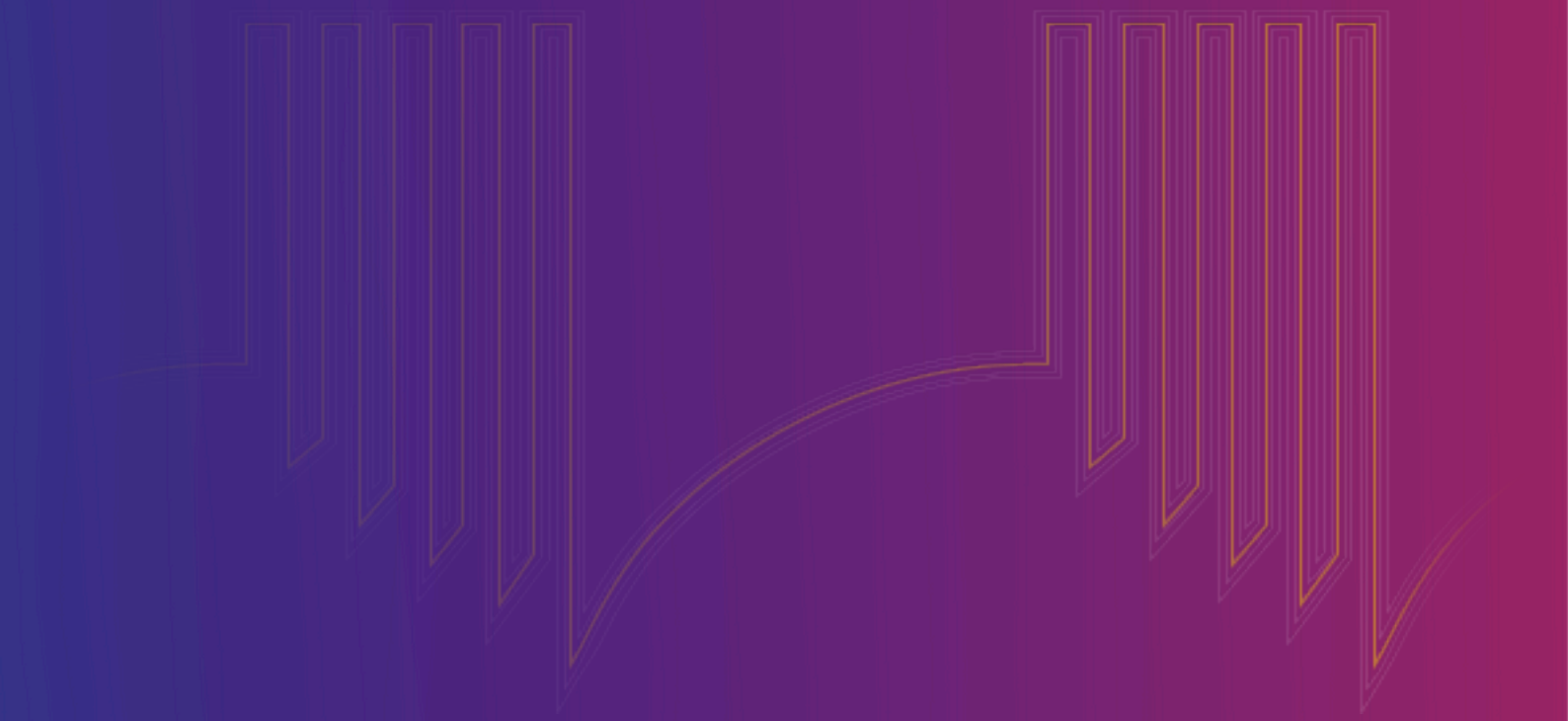
Abbott

BURSTDR™ STIMULATION



FOCUS ON YOUR PATIENT BY TREATING

THEIR PAIN INTENSITY AND SUFFERING USING

LOW-ENERGY AND LOW-MAINTENANCE

BURSTDR™ STIMULATION

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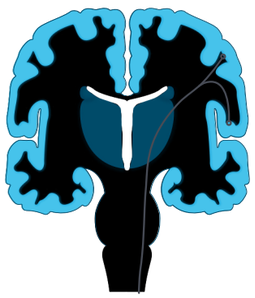
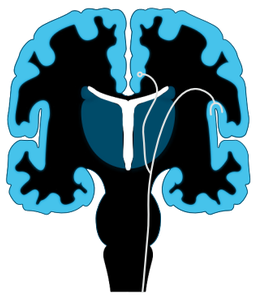
GLOBAL PAIN = **PAINFULNESS** + **SUFFERING** - **INHIBITION**

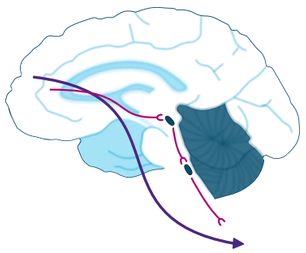
PAINFULNESS
Pain Intensity
Activates Lateral Pathway



SUFFERING
Attentionto Pain
Activates Medial Pathway



INHIBITION
Inhibition Activates
Descending Pathway



PAIN INTENSITY SCORE

VAS SCORE

PATIENT HEALTH AND WELL-BEING INDICATORS

MENTAL HEALTH
Measures an individual's pain experience by quantifying their thoughts and feelings

PHYSICAL
Measuresa patient's physical capability, rest and quality of sleep

SOCIAL
Measures apatient'sability to participate in social roles and activities

TREATING ALL DIMENSIONS OF CHRONIC PAIN

Help your chronic pain patients regain **quality of life** by uniquely **managing both pain intensity** and **suffering**.1† By managing all chronic pain dimensions, you **may improve your patients' success** by reducing the fear, frustration, anxiety and depression associated with the pain.1

BURSTDR™ STIMULATION,* EXCLUSIVELY FROM ABBOTT, IS A **PROVEN TECHNOLOGY** INSPIRED BY NATURE2 THAT ADVANCES NEUROSTIMULATION THERAPY BY OFFERING YOUR PATIENTS RELIEF FROM BOTH THE PHYSICAL PAIN AND THE EMOTIONAL SUFFERING† ASSOCIATED WITH THE PAIN.3

BurstDR™ Stimulation

PAIN IS MULTIDIMENSIONAL

Help your patients regain **better quality of life** by uniquely **managing both pain intensity** and **suffering**† with BurstDR™ stimulation.1 This may improve your patients' success by reducing the fear, frustration, anxiety and depression associated with the pain.1

LOW ENERGY AND LOW MAINTENANCE

BurstDR stimulation is a unique and proprietary waveform with a carry-over effect4 allowing it to be **dosed without sacrificing efficacy** and **optimizing battery longevity** .**

SIMPLICITY OF PROGRAMMING

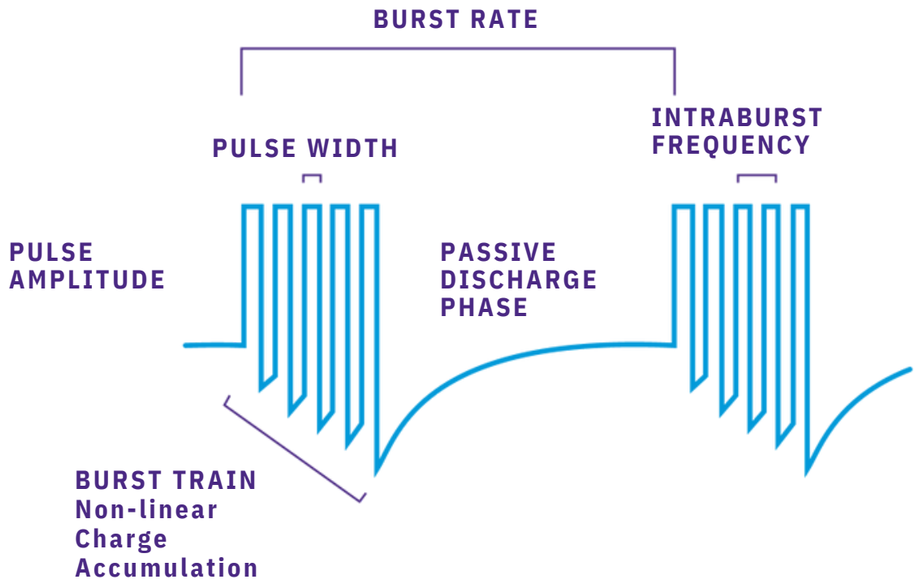
Patients and clinic staff **may spend less time** in programming BurstDR stimulation with BoldXR™ Dosing Protocol.5

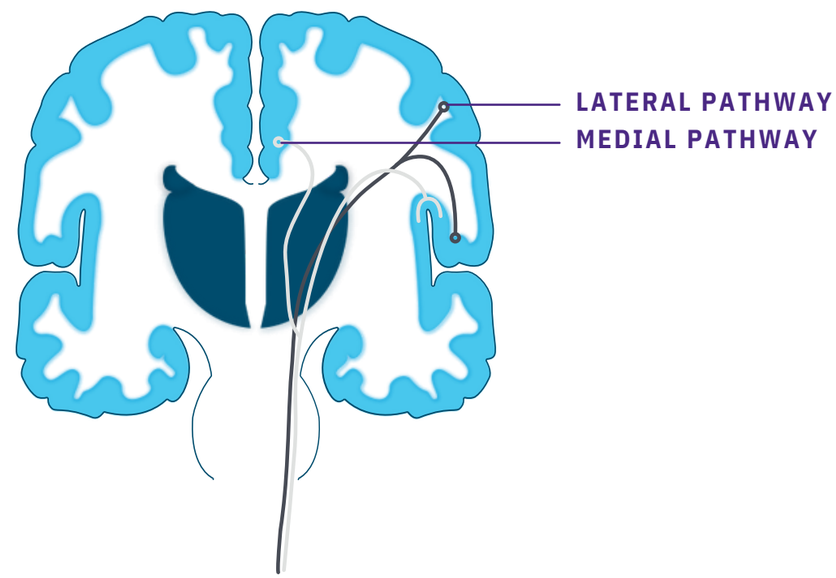
What is BurstDR™ Stimulation?

BurstDR™ stimulation uniquely mimics burst firing in the brain,2 giving patients relief from both the physical pain and the emotional suffering† associated with pain.3

BurstDR stimulation offers your patients superior*** pain relief over tonic stimulation3 and may improve patients' success by reducing the fear, frustration, anxiety and depression associated with their pain.1

Unlike traditional tonic stimulation, BurstDR stimulation has shown unique modulation of the medial pathway across multiple brain imaging studies.6-8





PAIN INTENSITY REDUCTION

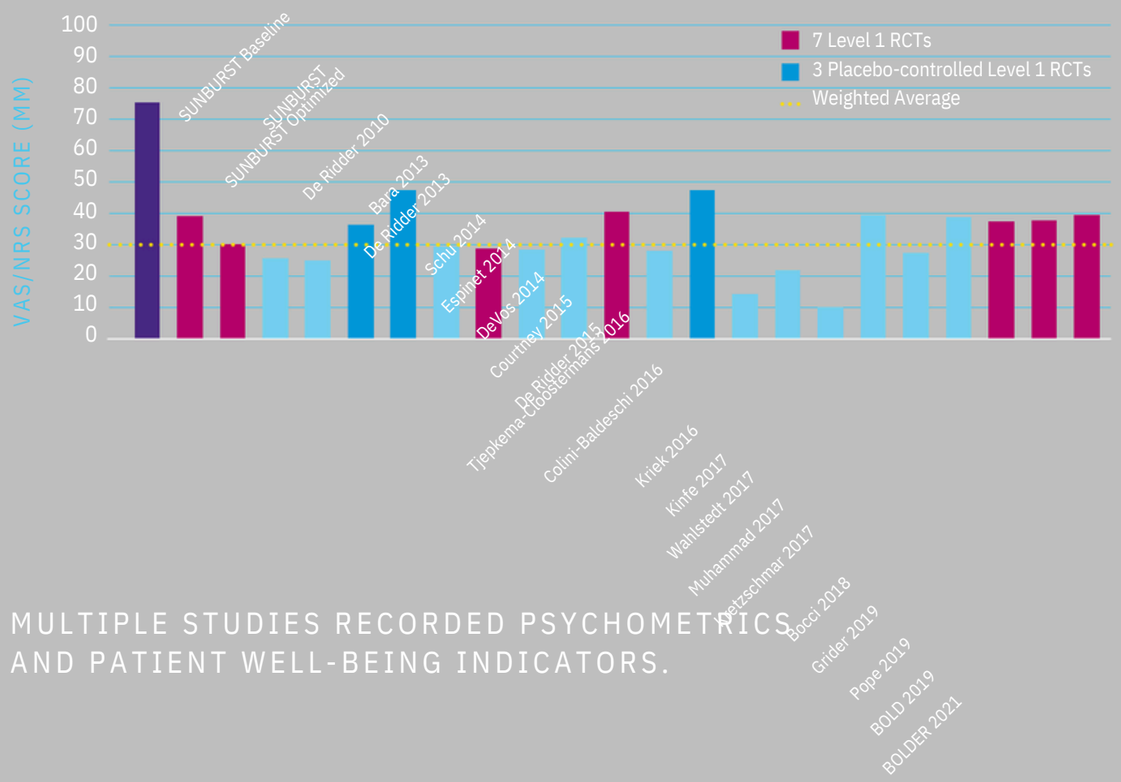
BurstDR™ stimulation delivers consistent, positive results, providing the patient better control of their pain intensity.3,5,9-31

PATIENT HEALTH AND WELL-BEING ENHANCEMENT

BurstDR™ stimulation impacts more than pain intensity, providing the patient better control of the emotional suffering† associated with the pain.

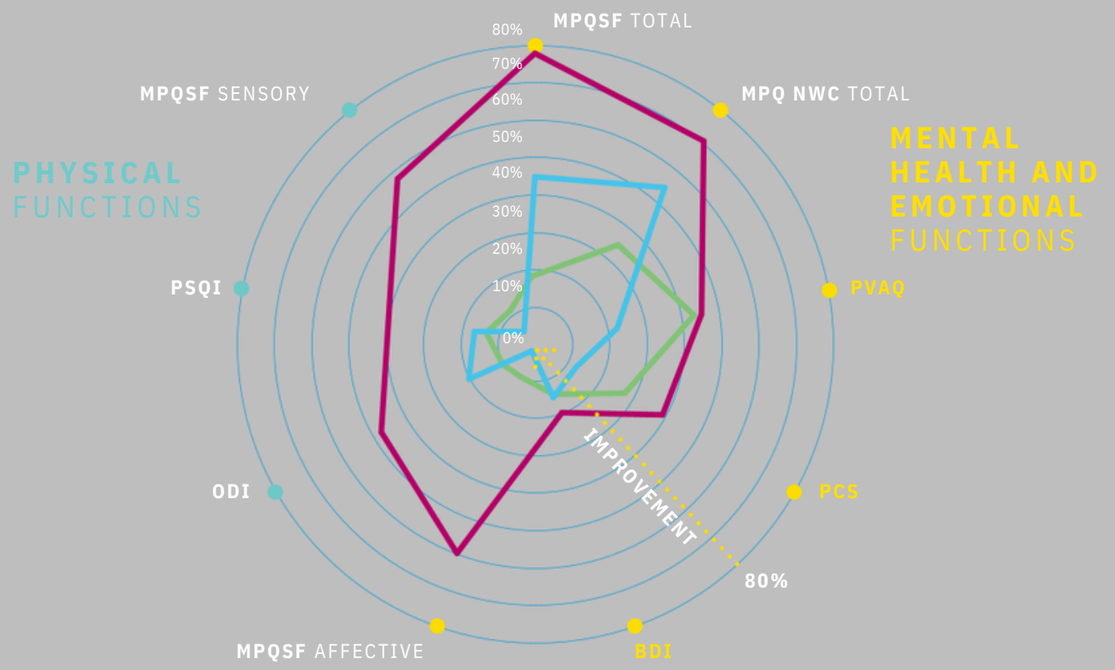
- Demonstrated significant improvement in physical functions
- Improved mental health functions
- Improved QoL and social well-being

1,000+ PATIENTS WERE STUDIED OVER 10 YEARS
ON 3 CONTINENTS.



MULTIPLE STUDIES RECORDED PSYCHOMETRICS
AND PATIENT WELL-BEING INDICATORS.

TOTAL PRO SCORE (%) OF A POOLED ANALYSIS OF
9 STUDIES WITH 209 PATIENTS32



PCS, PVAQ AND **BDI** SCORES ARE EXCELLENT INDICATORS OF
MEDIAL PAIN PATHWAY MODULATION.

BDI	Beck Depression Inventory	NWC	number of words chosen	PRO	patient-reported outcome
MPQ	McGill Pain Questionnaire	ODI	Oswestry Disability Index	PSQI	Pittsburgh Sleep Quality Index
MPQSF	McGill Pain Questionnaire Short Form	PCS	Pain Catastrophizing Scale	PVAQ	pain awareness and vigilance questionnaire

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BURSTDR™ STIMULATION

Supports Improved Outcomes Over Tonic Stimulation

GLOBAL PAIN =

PAINFULNESS
Pain Intensity
Activates Lateral Pathway

+

SUFFERING
Attention to Pain
Activates Medial Pathway

-

INHIBITION
Inhibition Activates
Descending Pathway

PAIN INTENSITY INDICATORS

proven in more than
23 studies involving
1,000+
patients
over 10 years
on 3 continents

PATIENT HEALTH AND WELL-BEING INDICATORS
(mental health, physical and social functions)

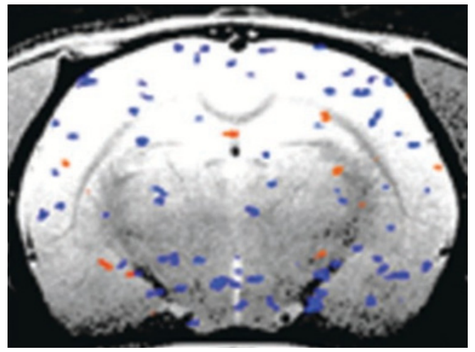
proven in more than
10 studies involving
337+
patients[32,33]

BurstDR™ stimulation is a unique and proprietary waveform with a carry-over effect4 allowing it to be dosed without sacrificing efficacy and optimizing battery longevity .**

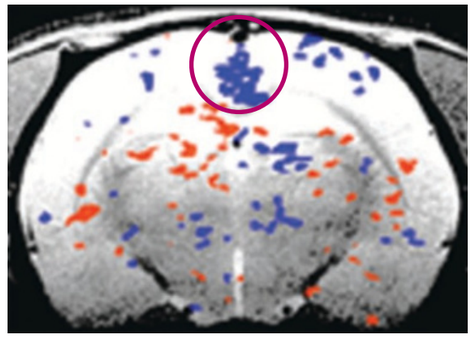
OPTIMIZATION OF THE BURSTDR™ STIMULATION WAVEFORM

Preclinical research of BurstDR stimulation found there is an observed carry-over effect.

BurstDR™ stimulation is effective even when stimulation is turned off. This unique characteristic of the waveform allows us to dose BurstDR stimulation without affecting the therapy outcomes.

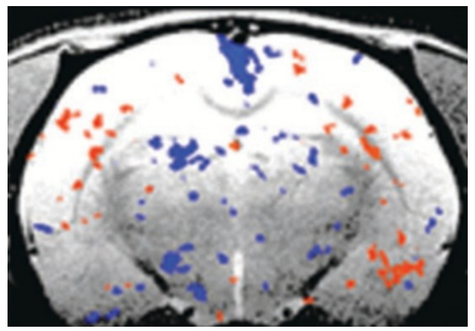


TONIC STIMULATION



BURSTDR™ STIMULATION

Unlike tonic SCS, BurstDR stimulation has an inhibitory effect in the anterior cingulate cortex.



DOSED BURSTDR STIMULATION

This effect persists even while dosing the input.

ANTERIOR CINGULATE
(Medial Pathway)

Dosing BurstDR™ stimulation allows us to provide your patients with low-energy, low-maintenance neuromodulation devices.

BOLDER DATA

100% of patients remained on dosed settings using 6 hours or less of stimulation per day at 6-month follow-up.31

- **Real-world evidence** (n = 195) supports the effectiveness of BurstDR stimulation with long stimulation-off intervals.

BASED ON THE BOLDER STUDY, AT 6 MONTHS [31]:

1.8
HOURS

Over 81% of patients remained at the ultra-low stimulation settings with BurstDR stimulation: 30 seconds on/360 seconds off stimulation (only 1.8 hours of stimulation per day).31

80%
OF PATIENTS

80% of patients improved across a multidimensional responder rate that considers both pain relief and QoL improvements with 1.8 hours of stimulation per day.31

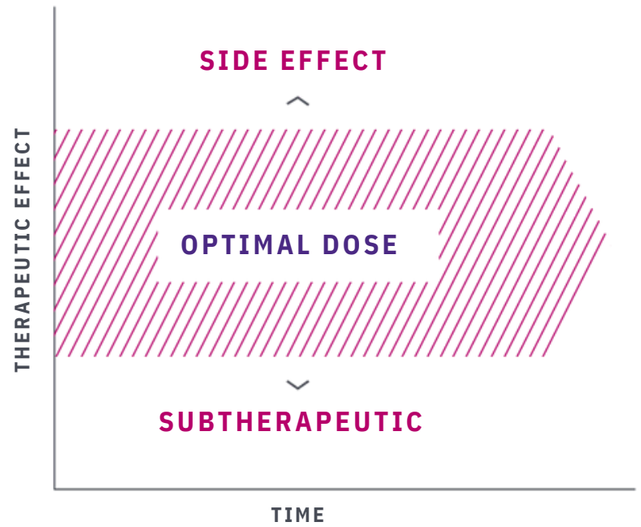
DOSED BURSTDR™ STIMULATION

- Delivered statistically significant reduction in pain27
- Led to improvement in patient well-being and QoL metrics27

LOWER THE DOSE. RAISE YOUR EXPECTATIONS.

Dosing BurstDR™ stimulation allows us to provide your patients with low-energy, low-maintenance neuromodulation devices.

- Proclaim™ XR Recharge-free SCS System, a low-maintenance system with a longevity of up to 10 years at the lowest dose**
- Prodigy MRI™ SCS System, a low-maintenance system



BE CONFIDENT IN THE THERAPEUTIC WINDOW.

Dosing stimulation can maintain therapeutic effect while lowering risk of overstimulation.27

SIMPLICITY OF PROGRAMMING WITH BOLDXR™ DOSING PROTOCOL

Patients and clinic staff **may spend less time** in programming BurstDR™ stimulation with the BoldXR™ Dosing Protocol.5

BOLDXR DOSING PROTOCOL: A LOW-ENERGY REVOLUTION*5*

The world's first standardized electronic dosing protocol for BurstDR stimulation is designed to improve patient experience.

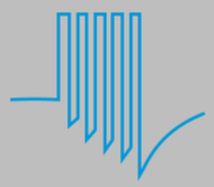
PROGRAMMING BURSTDR™ STIMULATION

Simple and effective subthreshold programming identifies the lowest therapeutic dose without sacrificing therapy effectiveness.

- Program BurstDR stimulation at the lowest dose, with 1.8 hours of stimulation per day:

  30 seconds on stimulation/360 seconds off stimulation.§

FREE YOUR STAFF AND YOUR PATIENTS FROM THE HASSLE OF CHANGING THERAPY PROTOCOLS BY SETTING YOUR PAIN PATIENTS AT THE LOWEST DOSE.



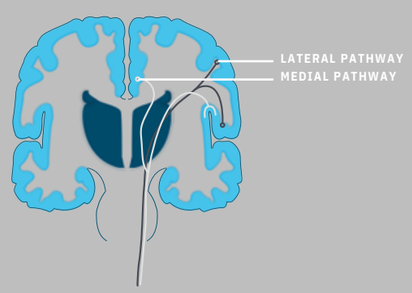
BURSTDR™ STIMULATION
is a proprietary waveform that is uniquely dosable.

BurstDR™ Stimulation

TREATS ALL PAIN DIMENSIONS

BurstDR™ stimulation consists of a proprietary waveform that mimics natural firing patterns in the brain.2

BurstDR stimulation allows patients to regain QoL by uniquely controlling both physical pain and emotional suffering.1†



23
STUDIES

PRODUCES CONSISTENT, SUPERIOR AND REPLICABLE RESULTS IN DIVERSE CLINICAL SETTINGS AROUND THE WORLD [3,5,9-31] ***

BurstDR™ stimulation is the only waveform with **level 1A evidence** showing superiority compared to tonic stimulation.

Further supporting data include:

- 1,000+ patients over 10 years on 3 continents
- 7 level 1 RCTs
- 3 placebo-controlled level 1 RCTs

10
QoL
STUDIES

IMPROVES MENTAL HEALTH, PHYSICAL AND SOCIAL FUNCTIONS[32,33]

More than 10 studies showed improvement in mental health, physical and social functions with BurstDR stimulation.

LOW ENERGY AND LOW MAINTENANCE

BurstDR stimulation is **effective** even after stimulation is **turned off**. **Target** the lowest therapeutic dose without sacrificing therapy effectiveness.4 BurstDR stimulation is delivered on low-maintenance recharge-free and rechargeable SCS systems.

SIMPLICITY OF PROGRAMMING

Patients and clinic staff may spend less time in programming BurstDR stimulation with BoldXR™ Dosing Protocol.5

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IFU	Instructions for Use
NRS	numeric rating scale
PGIC	Patient Global Impression of Change
QoL	quality of life
RCT	randomized controlled trial
SCS	spinal cord stimulation
VAS	Visual Analog Scale

1. De Ridder D, Adhia D, Vanneste S. The anatomy of pain and suffering in the brain and its clinical implications. *Neurosci Biobehav Rev.* 2021;130:125-146.
2. De Ridder D, Vanneste S, Plazier M, Vancamp T. Mimicking the brain: evaluation of St Jude Medical's Prodigy Chronic Pain System with Burst Technology. *Expert Review of Medical Devices*. 2015;12(2):143-150.
3. Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform. *Neuromodulation*. 2018;21(1):56-66.
4. Saber M, Schwabe D, et al. Rat fMRI brain responses to noxious stimulation during tonic, burst, and burst-microdosing spinal cord stimulation. Presented at: NANS Summer Series; 2018; New York, NY.
5. Deer TR, Patterson DG, Baksh J, et al. Novel Intermittent Dosing Burst Paradigm in Spinal Cord Stimulation. *Neuromodulation*. 2021;24(3):566-573.
6. Swadlow HA, Gusev AG. The impact of "bursting" thalamic impulses at a neocortical synapse. *Nature Neuroscience*. 2001;4(4):402-408.
7. De Ridder D, Vanneste S. Burst and Tonic Spinal Cord Stimulation: Different and Common Brain Mechanisms. *Neuromodulation*. 2016;19(1):47-59.
8. Yearwood TL, Falowski S, Venkatesan L, Vanneste S. Comparison of neural activity in chronic pain patients during tonic and burst spinal cord stimulation: A SUNBURST sub-study. Paper presented at: North American Neuromodulation Society and the Neural Interfaces Conference (NANS-NIC); June 25-29, 2016; Baltimore, MD.
9. De Ridder D, Plazier M, Kamerling N, Menovsky T, Vanneste S. Burst spinal cord stimulation for limb and back pain. *World Neurosurgery*. 2013;80(5):642-649.e641.
10. Slavin KV, North RB, Deer TR, Staats P, Davis K, Diaz R. Tonic and burst spinal cord stimulation waveforms for the treatment of chronic, intractable pain: study protocol for a randomized controlled trial. *Trials*. 2016;17:1-11.
11. Leong SL, De Ridder D, Deer T, Vanneste S. Potential Therapeutic Effect of Low Amplitude Burst Spinal Cord Stimulation on Pain. *Neuromodulation*. 2021;24(3):574-580.
12. De Ridder D, Vanneste S, Plazier M, van der Loo E, Menovsky T. Burst spinal cord stimulation: toward paresthesia-free pain suppression. *Neurosurgery*. 2010;66(5):986-990.
13. Courtney P, Espinet A, Mitchell B, et al. Improved Pain Relief With Burst Spinal Cord Stimulation for Two Weeks in Patients Using Tonic Stimulation: Results From a Small Clinical Study. *Neuromodulation*. 2015;18(5):361-366.
14. Schu S, Slotty PJ, Bara G, von Knop M, Edgar D, Vesper J. A prospective, randomised, double-blind, placebo-controlled study to examine the effectiveness of burst spinal cord stimulation patterns for the treatment of failed back surgery syndrome. *Neuromodulation*. 2014;17(5):443-450.
15. Tjepkema-Cloostermans MC, de Vos CC, Wolters R, Dijkstra-Scholten C, Lenders MW. Effect of Burst Stimulation Evaluated in Patients Familiar With Spinal Cord Stimulation. *Neuromodulation*. 2016;19(5):492-497.
16. Colini-Baldeschi G, De Carolis G, Papa A, et al. Burst stimulation for chronic low back and leg pain. Presented at: 8th World Congress of the World Institute of Pain; 2016; New York, USA.
17. Deer T, et al. Randomized, Controlled Trial Assessing Burst Stimulation for Chronic Pain: Two-year Outcomes from the SUNBURST Study. Poster presented at: North American Neuromodulation Society Meeting; 2018; Las Vegas, NV.
18. Bara B, Schu S, Vesper J. First results of Burst high frequency stimulation in failed FBSS stimulation patients. One year follow up. *Neuromodulation*. 2013;16(5):e136.
19. Espinet A, Courtney P, Mitchell B, et al. Burst spinal cord stimulation provides superior overall pain relief compared to tonic stimulation. *Pain Practice*. 2014;14(s1):114.
20. De Vos CC, Bom MJ, Vanneste S, Lenders MW, de Ridder D. Burst spinal cord stimulation evaluated in patients with failed back surgery syndrome and painful diabetic neuropathy. *Neuromodulation*. 2014;17(2):152-159.
21. Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJPM. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. *European Journal of Pain*. 2017;21(3):507-519.
22. De Ridder D, Lenders MW, De Vos CC, et al. A 2-center comparative study on tonic versus burst spinal cord stimulation: amount of responders and amount of pain suppression. *Clinical Journal of Pain*. 2015;31(5):433-437.
23. Kinfe TM, Muhammad S, Link C, Roeske S, Chaudhry SR, Yearwood TL. Burst Spinal Cord Stimulation Increases Peripheral Antineuroinflammatory Interleukin 10 Levels in Failed Back Surgery Syndrome Patients With Predominant Back Pain. *Neuromodulation*. 2017;20(4).
24. Wahlstedt A, Leljevahl E, Venkatesan L, Agnesi F. Cervical burst spinal cord stimulation for upper limb chronic pain: A retrospective case series. Poster presented at: 16th Annual Pain Medicine Meeting; 2017; Lake Buena Vista, FL.
25. Muhammad S, Roeske S, Chaudhry SR, Kinfe TM. Burst or High-Frequency (10 kHz) Spinal Cord Stimulation in Failed Back Surgery Syndrome Patients With Predominant Back Pain: One Year Comparative Data. *Neuromodulation*. 2017;20(7):661-667.
26. Kretzschmar M, Vesper J, Van Havenbergh T, et al. Improved pain and psychosocial function with Burst SCS: 1 year outcomes of a prospective study. *Neuromodulation*. 2017;20(7):e450.
27. Deer T. Efficacy of Burst Spinal Cord Stimulation Microdosing in a De-Novo Patient. Poster presented at: NAPA Pain 2019.
28. Bocci T, De Carolis G, Paroli M, et al. Neurophysiological Comparison Among Tonic, High Frequency, and Burst Spinal Cord Stimulation: Novel Insights Into Spinal and Brain Mechanisms of Action. *Neuromodulation*. 2018;21(5):480-488.
29. Grider JS, Harned M. Cervical Spinal Cord Stimulation Using Monophasic Burst Waveform for Axial Neck and Upper Extremity Radicular Pain: A Preliminary Observational Study. *Neuromodulation*. 2020;23(5):680-686.
30. Pope JE, Schu S, Sayed D, et al. Anatomic Lead Placement Without Paresthesia Mapping Provides Effective and Predictable Therapy During the Trial Evaluation Period: Results From the Prospective, Multicenter, Randomized, DELIVERY Study. *Neuromodulation*. 2020;23(1):109-117.
31. Deer T, Wilson D, Schultz D, et al. Ultra-Low Energy Cycled Burst Spinal Cord Stimulation Yields Robust Outcomes in Pain, Function, and Affective Domains: A Subanalysis From Two Prospective, Multicenter, International Clinical Trials. *Neuromodulation*. July 2021.
32. Chakravarthy K, Malayil R, Kirketeig T, Deer T. Burst Spinal Cord Stimulation: A Systematic Review and Pooled Analysis of Real-World Evidence and Outcomes Data. *Pain Medicine*. 2019;20:S47-S57.
33. Deer T, Falowski S, Moore G, et al. Passive Recharge Burst Spinal Cord Stimulation provides sustainable improvements in pain and psychosocial function: 2-year results from the TRIUMPH study. *Spine*. 2021. doi: 10.1097/BRS.0000000000004283.

*BurstDR™ stimulation, patented technology exclusively from Abbott, is also referred to as burst stimulation in clinical literature.
**Up to 10 years of battery longevity at the lowest dose setting: 0.6mA, 500 Ohms, duty cycle 30s on/360s off. NOTE: In neurostimulation therapy, 'dose' refers to the delivery of a quantity of energy to tissue. Safety comparisons and specific dose-response curves for each dosage have not been clinically established. Refer to the IFU for additional information. Hassle-free means recharge-free.
***Superiority when compared to traditional tonic stimulation in the SUNBURST Study.

§For further information, refer to the BoldXR™ Dosing Protocol document.
†Pain and suffering as measured by VAS.

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Neuromodulation.Abbott

Brief Summary: Prior to using Abbott devices, please review the Clinician's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: Spinal cord stimulation 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 and intractable low back and leg pain.

Contraindications: Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems or other active implanted devices, magnetic resonance imaging (MRI), electrosurgery, explosive and flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Unpleasant sensations, undesirable changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain at the electrode or IPG site, seroma at IPG site, allergic or rejection response, battery failure. Clinician's Manual must be reviewed for detailed disclosure.

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