



# DISTINCT

## LOW BACK PAIN

### STUDY



#### A DISTINCTLY DIFFERENT WAY TO TREAT CHRONIC LOW BACK PAIN

Low back pain is the world's leading cause of years lost to disability.<sup>1</sup> Often, there is not a specific anatomical cause that can be treated with spine surgery.

Neurostimulation is a well-established pain treatment used by doctors for more than 50 years. One of Abbott's most advanced forms of this therapy is BurstDR™ stimulation. It works by using mild electrical pulses delivered by a small implant to change pain signals as they travel from the spinal cord to the brain.<sup>2</sup>

The DISTINCT study is designed to understand how BurstDR stimulation can relieve pain and improve physical function in people with chronic low back pain who have not had back surgery and in people who are not good candidates for surgery.

When you participate in a clinical trial, you are joining the front line against a disease. **If you have suffered with low back pain for more than 6 months and have been told you are not a candidate for spine surgery, ask your doctor if the DISTINCT study is right for you.**

#### PRE-SCREENING QUESTIONS

DISTINCT will evaluate the efficacy of spinal cord stimulation to relieve pain and improve physical function in people with chronic low back pain who have not had back surgery and for whom other treatments, such as medication, physical therapy and injections, have failed. This study will randomize participants to either conventional medical management or spinal cord stimulation for 6 months. After 6 months, participants may cross over to the treatment arm of the study.

##### In order to qualify for the study, your answers to the following must be YES:

1. I have chronic (at least 6 months) low back pain and have been told that I am not a candidate for spine surgery.
2. I have tried multiple therapies in the past 6 months that have not adequately helped me.
3. I have not had surgery for my back pain or pain that shoots down my leg.
4. On a scale from 0=no pain to 10=worst pain, my back pain is at least a 6.
5. My back pain is the main problem. I may have some leg pain, but it is not as bad as my back pain.
6. I do not have fibromyalgia or widespread pain (all over my body).

##### And your answers to all of the following must be NO:

1. My back pain is due to a tumor, infection or damage to my spinal cord
2. I have severe scoliosis
3. I have tried other neuromodulation devices
4. I am taking pain medications that add up to a daily dose of more than 50 morphine equivalents
5. I have or have had an implantable drug pump
6. My BMI is >40
7. I am receiving worker's compensation or am in litigation
8. I have a known allergic reaction to implanted materials
9. I have a neurological deficit (e.g. foot drop)

#### LOCATE A CLINICAL STUDY SITE NEAR YOU

[USE MY LOCATION](#)

**References**

1. Buchbinder R, van Tulder M, Öberg B, et al. Low back pain: a call for action. *Lancet*. 2018;391(10137):2384-2388.
2. 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

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

MAT-2011119 v1.0



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MAT-2011056 v1.0