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Indications for Use

Rx ONLY CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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Indications for Use

The Boston Scientific Spinal Cord Stimulator (SCS) Systems are 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, Complex Regional Pain Syndrome (CRPS) Types I and II, intractable low back pain and leg pain.

Associated conditions and etiologies may be

- radicular pain syndrome,
- radiculopathies resulting in pain secondary to failed back syndrome or herniated disc,
- epidural fibrosis,
- degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions),
- arachnoiditis,
- multiple back surgeries.

Note: CRPS I was previously referred to as Reflex Sympathetic Dystrophy (RSD) and CRPS II was previously referred to as causalgia.

Refer to the *Information for Prescribers* manual for your SCS system for contraindications, warnings, precautions, adverse events summary, Physician Instructions, sterilization, component disposal, contact information for Boston Scientific, information regarding the Patient Identification card, FCC rules and clinical studies supporting clinical use of the neuromodulation system.

For other device-specific information not included in this manual, labeling symbols, and warranty information, refer to the appropriate DFU for your SCS System as listed on your Reference Guide.

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Legal Manufacturer

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