Directions for Use

Fake Medical Device System©

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[Logo]

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Intended Use

The [medical device]© section of this Directions for Use (DFU) provides procedures and and information applicable to the [medical device]© System and accompanying [supplementary system]. Each major section of the DFU provides information and instructions for the product.

The [medical device]© system is indicated for spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion and dorsal horn of the spinal cord. Stimulation of these structures may result in pain relief for patients suffering from chronic, intractable pain.

The [medical device system] features a Programmable Controller Unit (PCU) for initiating stimulation on the spinal column. The system allows for up to 20 patient-specific stimulation setting profiles. These may programmed by a licensed healthcare practitioner. Each profile contains a stimulation amplitude, pulse width, pulse frequency, stimulation cycling, and a stimulation pattern setting.

Information about each setting can be found in the subsequent PCU section.

Documentation provided by [company] may reference products not present in your healthcare provider's facility or not yet available for sale in your area.

WARNING

Read all instructions before using the [medical device system].

Device Description

The [medical device system] is an advanced, programmable device designed to provide targeted electrical stimulation for the management of chronic, intractable pain.

Implantable Component and Leads

The implantable component is a small, battery-powered device that generates electrical pulses for stimulation on the spinal cord. It is surgically implanted under the skin. It is made of [material] and contains a rechargeable battery, a microprocessor, and sensor module for near-field communication (NFC) with the battery charger. NFC produces non-ionizing waves that transit through the skin.

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The leads are thin, insulated wires that deliver the electrical pulses from the implatable component to the targeted spinal cord or dorsal root anglion areas.

Wireless Charger and Base Station

The wireless charger is a portable, cordless charging device used to recharge the implantable component's battery. The charger uses inductive coupling to transfer energy wirelessly through the skin to the component. The charging process is simple, fast, and can be performed by the patient without the need of a healthcare practitioner.

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The base station is a separate device that acts as the housing unit for the wireless charger when not in use and is designed to recharge the wireless device. It is powered by a standard wall outlet and includes an LED indicator to display the charging status of the wireless charger.

Device Description (cont.)

Programmable Control Unit (PCU)

The PCU is a handheld device that provides licensed healthcare practitioners with additional control and customization options for the [medical device] system. It features a colourless screen and intuitive navigation buttons, allowing practioners to fine-tune stimulation parameters, create custom stimulation patterns, and monitor patient progress.

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