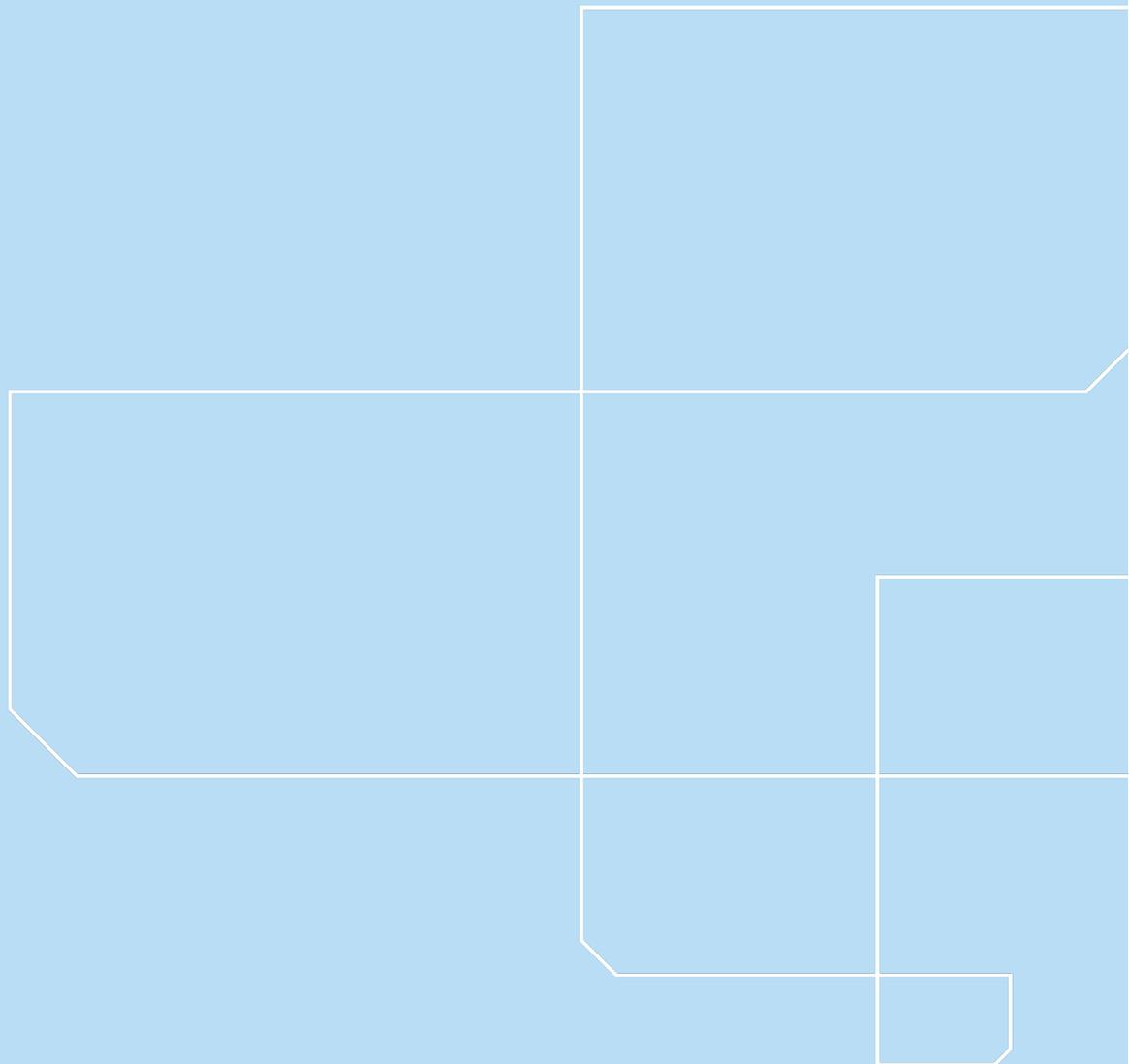


REDUCING RELIANCE ON OPIOIDS: SPINAL CORD STIMULATION FOR CHRONIC PAIN

How to choosing the right partner can enable you to bring safer, more effective treatments to market.



Worldwide, more than 30% of the population suffers from chronic pain, disproportionately affecting women, elderly adults, and people in rural communities.¹ Chronic pain, which lasts for more than three months, is the foremost source of disability is connected to reduced life expectancy,¹ and is a primary driver of the opioid crisis plaguing society. The four most common types of chronic pain are back, neuropathic, joint, and headaches, with back pain being the most prevalent. It is estimated that 1 in 10 adults over 30 years of age experience neuropathic pain requiring pain management, traditionally using medications such as opioids.²

Approximately 70% of all drug-related deaths can be attributed to opioid misuse. It is estimated that 3.8% of Americans abuse opioids each year, and opioid-associated overdose deaths increased by 519.38% from 1999 to 2019.³ As there is a large push to identify alternative treatment options for chronic pain and reduce reliance on opioids, spinal cord stimulation (SCS) is one therapy being evaluated for this purpose.

EMERGING THERAPY

One area of increasing interest in pain management is neuromodulation, using electrical therapies to stimulate parts of the brain or nervous system.⁴ More specifically, SCS has a growing body of evidence indicating its efficacy in treating patients with chronic pain. SCS can relieve neuropathic pain, pain caused by damage to nerves, such as radicular, peripheral neuropathy, phantom or ischemic limb, angina, or complex regional pain syndrome (CRPS).⁵

SCS treatment involves two procedures, one to test the device's efficacy (a trial procedure) in reducing pain and one for the final implantation of the device, should it be successful. The device consists of electrodes and a pulse generator, with the electrodes positioned in the epidural space and the pulse generator subcutaneously.⁶ The electrical pulses delivered through the electrodes interrupt pain signals between the spinal cord and brain, relieving pain for the patient.⁶

The two primary types of spinal cord stimulators are conventional implantable pulse generators (IPG) and rechargeable IPGs.⁶ These IPGs are battery-operated, one with a replaceable battery, requiring additional procedures, and one that can be recharged without additional procedures.⁶

There are different types of leads used in these devices, including trialing, percutaneous, and paddle and leads. Trialing leads are used in trial or short-term implantations, whereas percutaneous and paddle leads are used in permanent implantations. Although paddle leads are superior in terms of stability and lack of movement, percutaneous leads are used most frequently as paddle leads are more invasive, requiring open surgery.⁵

DEVICE DEVELOPMENT

Spinal cord stimulators are considered class II medical devices. Research indicates this class of devices takes an average of three to seven years to bring to market, from concept through approval, and approximately \$2-5 million in development and engineering costs (of a total \$30 million).⁷ This process can be alleviated by outsourcing all or part of the development process. Choosing a partner that serves as an extension of one's team and brings significant expertise in design, development, and manufacturing can help bring devices to the market faster.

CHOOSING THE RIGHT PARTNER

Heraeus Medevio is a market-leading device outsourcing partner, facilitating increased speed to market for medical device OEMs, and employing a variety of procedures and areas of expertise.

EXPERTISE IN A WIDE VARIETY OF LEAD TECHNOLOGIES

Expand the capacity and capabilities of your development teams with support from our experts from concept to design, prototyping, through large-scale manufacturing. Our team brings unmatched expertise in medical alloys, advanced thermoplastic micro-insert molding, and manufacturing to handle the most complex projects and products.

Heraeus Medevio can manage a wide range of assembly needs, including Distal Electrode Assemblies (neurological or cardiac) and Proximal Contact Assemblies (neurological or cardiac).

DESIGN FOR MANUFACTURING

With extensive manufacturing experience, Heraeus Medevio knows how critical it is to design products with efficient and scalable manufacturability. Our team will help you optimize your design through prototyping and a pilot line that is mirrored in production, reducing risk and saving time.

ROBUST QUALITY SYSTEMS

Heraeus Medevio offers a full range of in-house product performance testing to support the design and development process as well as compile the testing required to secure regulatory clearances and approvals. Doing this in-house allows us to drastically reduce development and regulatory timelines.

Creation and execution of performance test plans to support development activities and regulatory submissions are determined for each device manufactured by Heraeus Medevio. Testing is performed according to ISO, EN, DIN, ASTM, and applicable regulatory standards, including FDA requirements (e.g., 510(k) submissions, IDE applications, etc.).

Our unmatched regulatory support includes:

- FDA device clearance (510(k), PMA, etc.)
- CE marking (technical file preparation, post-market activities, etc.)
- Support in clinical trial approvals, clinical trial support, and set-up and maintenance of quality management systems
- For startup customers who do not yet have an ISO-certified quality management system, we offer to hold regulatory approvals (e.g., CE mark) for products on behalf of our customers.

VERTICALLY INTEGRATED SUPPLY CHAIN

Reducing the number of suppliers required removes complexity, can lower cost, and can increase speed to market. Heraeus Medevio manufactures everything from components and sub-assemblies to fully market-ready devices. In addition, as part of the Heraeus Group, Heraeus Medevio can in-source many parts needed for development.

LET'S CONNECT

Schedule your free consultation today to go over your concepts and requirements. We will then create an end-to-end plan tailored to your project.

To get started, complete our contact form, and our team will contact you.

APPENDIX

Citations

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