

F R O S T & S U L L I V A N

NUVECTRA™

2017 North American Spinal Cord Stimulation New Product Innovation Award

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BEST
2017 PRACTICES
AWARD

NORTH AMERICAN
SPINAL CORD STIMULATION
NEW PRODUCT INNOVATION AWARD

Background and Company Performance

Industry Challenges

Significant Public Health Concern, Largely Underserved Market

Pain is the leading reason that patients seek medical treatment worldwide, affecting at least 10% of the global population¹. Chronic pain is largely underdiagnosed and undertreated; approximately 80% of the world population receives inadequate therapies for moderate-to-severe pain². In the United States (US), chronic pain affects over 100 million Americans, with an estimated annual economic burden nearing \$635 billion, including both treatment and lost productivity³.

Although pain is a universal experience, pain assessment is subjective, adding to treatment complexity and aggravating an already staggering problem. In 2013, Frost & Sullivan estimated the global chronic pain market at \$50.2 billion. Significantly underserved given its size, this segment offers a huge opportunity for companies that effectively penetrate the market.

Spinal Cord Stimulation: Safe Alternative to Long-term Opioid Analgesics

Opioid analgesics are often the treatment of choice to relieve chronic and severe pain. However, comprehensive clinical evidence as to the effectiveness of opiates is lacking, and long-term opioid use can have serious consequences—e.g., reduced function, addiction, overdose, and death. The Centers for Disease Control and Prevention recently released opiate prescription guidelines aimed at primary care physicians (PCPs)—who dispense nearly half of all opiates—attempting to mitigate the use of these drugs in the midst of a painkiller epidemic.

Physicians, patients, and third-party payers all are aware of the side effects and the risks of abuse and dependency associated with opioid-related pain medications. The growing dissatisfaction among all healthcare stakeholders over conventional drug therapies is driving the demand for non-drug alternative treatments for chronic pain.

Neurostimulation therapies deliver electrical impulses to modulate brain activity in certain areas or specific nerves to achieve desired therapeutic outcomes. Spinal cord stimulation (SCS) is a reversible and a proven neuromodulation technology primarily used in refractory chronic pain treatment, garnering a reputation as an effective and safe therapy over the past four decades.

SCS delivers mild electrical signals to the epidural space near the spine through leads. A tingling sensation due to the electric signals masks chronic pain by blocking pain messages from reaching the brain. SCS systems typically include a battery-powered, implantable pulse generator (IPG)—pacemaker-like device implanted in the upper

¹ *The Global Burden of Chronic Pain*: <http://www.asahq.org/resources/publications/newsletter-articles/2014/june-2014/>

² *Access to pain treatment as a human right*: http://www.who.int/medicines/areas/policy/access_noncommunicable/AccesstopaintreatmentasahumanrightBMCMed_Lohman_2010.pdf

³ <https://nccih.nih.gov/health/pain/chronic.htm>

buttock—connected to leads in the epidural space.

Frost & Sullivan estimates that the SCS sector in the US will be at nearly \$1.5 billion by 2018. Although a mature market, increasing disease prevalence, a growing demand for innovative alternative therapies, and expanded SCS awareness from wider patient acceptance and technology adoption will drive high market growth.

New Product Attributes and Customer Impact of Nuvectra

Headquartered in Plano, Texas, Nuvectra develops next-generation neurostimulation technologies for the management and treatment of various neurological disorders. The company's first commercial offering, the Algovita® SCS System, is CE marked and approved by the Food and Drug Administration (FDA) in November 2015 to treat chronic pain of the trunk and limbs.

Algovita®: Next-generation Spinal Cord Stimulation System

The Algovita® SCS system includes 24-channel rechargeable IPGs, a comprehensive lead portfolio—novel stretchable coil design and different lead configurations—and wireless programmers in a compact design for convenient and portable use.

The Algovita® SCS system combines multiple current sources with the broadest parametric range set (pulse width, frequency, and amplitude) of any system currently in the market to enable more personalized therapies. The system's electronic architecture—IPG features—allows greater specificity than currently approved, delivering stimulation to defined neural targets; while its broad parametric set provides a unique range of therapeutic options, e.g., low stimulation output, higher frequencies, or a pulse train of stimulation delivery to increase treatment effectiveness. Wireless, portable patient and physician programmers—based on the Medical Implant Communication Service (MICS) band—allow external program adjustments.



Courtesy of Nuvectra™

Intelligent Innovation

Nuvectra's development efforts focus on patient-centered innovation. The combination of electronic architecture, IPG capabilities, and telemetry not only enable agile, individually tailored SCS therapy for a range of chronic patients, but lead to an upgradable and expandable platform responsive to market changes. As research and stimulation

mechanisms evolve, Nuvectra has the potential to update Algovita® externally, avoiding additional surgical interventions to the patient while leveraging the latest therapies for optimal care. User-friendly control design and intuitive operation further showcase Nuvectra's commitment to "intelligent innovation."

"Innovation is a construct of multiple elements—inclusive of creativity, common sense, and thoughtfulness—applied to challenges and needs as opposed to innovation for innovation sake. Our [Nuvectra's] platform not only considers capabilities and usability but the system's upgradability downstream, enabling continued innovation around the patient."

-Tom Hickman, Executive Vice President of Marketing, Nuvectra

Convenient, Easy, and Simple

The PCP refers patients to a pain physician or neurosurgeon who ultimately determines the most appropriate treatment option based on the patient's needs. After discussing options with patients and determining SCS viability, physicians conduct a 3 to 7-day trial by placing percutaneous leads to evaluate the risk-benefit of the SCS therapy prior to implantation.

After implantation, physicians work along with Nuvectra's representatives during programming sessions with the patient to set the therapy configuration that effectively relieves their pain. Physicians continue to work closely with patients, over weeks or months, to optimize the treatment.

Algovita® enables physicians to increase or decrease therapy parameters—similar to changing the volume in a stereo, but in this case amplitude or frequency—moving towards significant personalized patient stimulation. Physicians can design multiple programs to provide patients with choices based on their daily experiences and pain levels, further tailoring the treatment to individual needs. Patients select the preferred program at any given time from a pocket-size controller that connects wirelessly to the IPG.



Nuvectra's close work with physicians and patients results in immediate feedback from both perspectives. Physicians appreciate Algovita®'s breadth of capabilities, usability, and the ease of lead implantation; while patients like the system's effectiveness and the portable programmer's easy-to-use interface. "The Algovita system has been a great addition to my practice and has enhanced the options I am able to provide my patients. The stretchable lead design and the ability to have leads span 3-vertebral body levels makes placement efficient with coverage of low back, legs and feet. In addition to the unprecedented coverage the broad therapy options provided by the IPG offers flexibility for patients to get excellent pain coverage in both the short and long terms.", said Jeffery Rowe, M.D., Main

Line Spine, King of Prussia, Pennsylvania.

Innovative Neurostimulation Platform Fit for the Future

Next-generation technologies, expanding awareness, and successful clinical outcomes drive growth in the neurostimulation market. In 2013, Frost & Sullivan's research showed that companies must capitalize on existing products and capabilities to improve therapies and cater to multi-indication diseases versus disease-specific technologies to increase penetration and gain market share.

Nuvectra's broad-based neurostimulation platform positions the company for accelerated future growth. In particular, the company's improved therapy delivery system—including enhanced features for a simple physician and patient user experience—and the platform's powerful, upgradable versatility—enables different therapeutic approaches and markets. The company is finalizing its next offering, a sacral nerve stimulation system for incontinence, which it expects to submit for FDA and CE approval in the near-term. Nuvectra is also working with a strategic partner to move into the deep brain stimulation market as well. The company anticipates that over time, other indications and opportunities to apply its technology will continue to emerge.

Conclusion

In the United States, chronic pain affects over 100 million Americans. Conventional treatments primarily rely on opioid use, which leads to a variety of safety risks, including reduced function, addiction, overdose, and even death. Spinal cord stimulation (SCS) is becoming a widely used non-drug alternative treatment for chronic pain conditions.

Nuvectra's flagship product, the Algovita® SCS System, uniquely combines electronic architecture, implantable pulse generator capabilities, and telemetry to enable agile, individually tailored SCS therapy for a range of chronic patients. The system allows physicians to design multiple treatment programs, empowering patients to select therapy options based on daily-life pain experiences. Moreover, Algovita®'s upgradable and expandable platform is responsive to market changes, providing non-invasive updates to implement the latest therapies for optimal care.

With its commitment to advancing next-generation neurostimulation technologies, Nuvectra earns Frost & Sullivan's 2017 North America New Product Innovation Award in the spinal cord stimulation market.

Significance of the New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market, and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Key Benchmarking Criteria

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors— New Product Attributes and Customer Impact—according to the criteria identified below.

New Product Attributes

- Criterion 1: Match to Needs
- Criterion 2: Reliability
- Criterion 3: Quality
- Criterion 4: Positioning
- Criterion 5: Design

Customer Impact

- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



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