

AVACEN[®]
medical

2017 European
OTC Fibromyalgia Pain Management Devices
New Product Innovation Award

FROST & SULLIVAN

BEST
2017 PRACTICES
AWARD

EUROPEAN OTC FIBROMYALGIA
PAIN MANAGEMENT DEVICES
NEW PRODUCT INNOVATION AWARD

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Background and Company Performance

Industry Challenges

Fibromyalgia is characterized by progressive and widespread chronic pain. According to the National Fibromyalgia Association, the condition affects approximately 200 to 400 million people worldwide. The estimated prevalence of fibromyalgia in the general population is 2 to 5%. In both community and clinical settings, 85 to 90% of sufferers are women, many middle-aged. Besides the chronic pain patients endure, fibromyalgia also imposes a large economic burden on public and private healthcare providers.

The FDA has approved three prescription medications to treat fibromyalgia pain, pregabalin, duloxetine, and milnacipran, and patients may also take analgesics or nonsteroidal anti-inflammatory drugs (NSAIDs) to help relieve the pain. However, various studies suggest a need for alternative non-invasive treatments or adjunct therapy that can help alleviate pain in fibromyalgia patients. A randomized placebo-controlled study showed that fibromyalgia patients reported modest improvements in pain, tender points, fatigue, and sleep after electro-stimulation, which further supports the need for device-based therapies.

One device-based approach, anodal transcranial direct current stimulation, a non-invasive approach that uses low electrical currents to stimulate the brain via electrodes, can help improve pain scores and quality of life for fibromyalgia patients. However, this device treatment cannot be performed at home and requires medical supervision.

Research studies indicate that arteriovenous (AV) shunts play a major role in the fibromyalgia pathology for extremities. However, the treatment of fibromyalgia remains challenging, and the underlying pathology is poorly understood. Studies show that blood vessels in the hand can be distended by exposure to negative pressure and that the application of superficial heat to the mechanically-distended tissues increases blood flow throughout the hand. However, no approved devices exist in the market at the moment, except for AVACEN Medical's AVACEN 100.

New Product Attributes and Customer Impact

Match to Needs



The AVACEN 100 is a Class II medical device that utilizes the AVACEN Treatment Method, a drug-free alternative form of non-invasive, augmentative dry heat device-based therapy that aims to provide effective treatment for the widespread pain associated with fibromyalgia.

The method involves active heat assisted by negative pressure applied to the palm of the hand of normothermic patients. Heat is exchanged at the

naturally occurring AV shunts of the hand. The device utilizes these AV shunts to rapidly infuse heat into the circulatory system. In addition to the heat applied to the surface of the palm, negative pressure is applied with the help of a vacuum chamber in the device, which enhances the continued exposure of blood to the warmed surface. This mechanism increases the blood flow and microcirculation, thereby allowing muscle and skin tissue to acquire proper nutrition while promoting waste removal.

The CE Mark approval for the AVACEN 100 allows AVACEN Medical to market the product to the European Union's 28 member countries where many prescription drugs available in the United States have been rejected by regulatory officials for treating widespread fibromyalgia pain. Currently, there are not many CE-approved over-the-counter (OTC) medical devices available in the market, and there are no other approved OTC devices for widespread fibromyalgia pain management in Europe.

Reliability and Quality

AVACEN 100 is FDA-cleared for marketing in the United States and received the CE Mark and Health Canada approval for widespread fibromyalgia pain management in Europe and Canada in 2017. A recent peer reviewed clinical efficacy study published in 2017 reported that out of 22 patients who were evaluated, those who received treatment for 15 minutes twice a day demonstrated an overall reduction of more than 40% in widespread pain index scores after 28 days. Of these subjects, 93% reported a reduction of 29.4% or more in widespread pain index scores. Also, 62% reported a lower tender point count of two or more points, and 57% reported a reduction of 20% or more in overall symptom severity score rating. With more than 2 million treatments using the device, there has been no adverse effect reported, which shows that the device is extremely safe and reliable.

Design

AVACEN Medical holds 13 patents. The AVACEN 100 device contains two components, a vacuum chamber and a heat-transfer element. The digital panel on the device provides instructions for use in English, French and Spanish, and the simple one-touch button makes it easy to operate for anyone from children to seniors. The device microprocessor manages the non-invasive and safe continued infusion of heat into the circulatory system with the help of more than 4,000 programmed firmware instructions and has a useful life of five years. In November 2015, National Pain Report published an article on AVACEN 100, mentioning that it is the world's first non-invasive device that allows patients to treat their entire body from a single convenient body location (the palm).

Positioning

The National Pain Report article mentions that the device integrates the combined health benefits of a dry heat sauna and a hyperbaric oxygen treatment and may well be the cost-effective solution chronic pain patients have been searching for. Since the device is drug-free, it significantly reduces the economic burden on patients. For example, according to research titled "The Iceberg Nature of Fibromyalgia Burden: The Clinical and Economic Aspects," published in Journal of Pain in 2015, the average annual direct cost for a

fibromyalgia patient ranges from \$2,000 to \$10,000 based on severity. In comparison, the one-time AVACEN device cost is approximately \$3,000, and it has a useful-life of five years or more. Thus, the device holds significant economic advantages over competing drug therapies.

AVACEN 100 is the only approved OTC medical device that non-invasively increases microcirculation systemically by heating the blood temperature marginally without adverse effects. Improved microcirculation solves a myriad of problems, especially for people over 40 years old as over 80% of this population has a deficient or compromised microcirculatory system that leads to various pain-related complications. By positioning itself as a responsible OTC market player, AVACEN aims to address patient needs free of challenges and restraints. Going forward, the company is preparing itself and building the capabilities necessary to convince the hospital and medical community of its product's many benefits and to expand from OTC to the professional market as a standard of care.

Customer Ownership Experience

The key value proposition of this solution is its safety (no adverse effects) and efficacy compared to other existing products in the market where adverse effects include vertigo, headache, nausea, and skin irritation at the site where electrodes are used. Moreover, adverse effects of drugs impact over 10 to 15% of the patient population.

AVACEN 100 has demonstrated absolutely no reported adverse effects on patients treated so far. The key benefits for patients are cost effectiveness, ease of use, and systemic treatment. Some of the major drawbacks with existing devices in the market are either they are not easy to use or are invasive in nature, especially for patients above 65 years of age. Some require constant supervision and are generally expensive. Further, existing non-invasive devices such as pulsed electromagnetic fields do not have the capacity to penetrate deeply enough throughout the entire human body and are not systemic.

In contrast, AVACEN 100 is the only non-invasive OTC device with proven efficacy and safety currently available in the OTC market. Recently, AVACEN 100 was credited with saving the limb of a patient at a major university hospital who was given a 1 to 2% chance of retaining the limb by the attending physician. Undoubtedly, the product is very unique and has already gathered much interest, not just among pain management professionals but also from other clinical specialists such as those working in orthopaedic, diabetes, and wound healing areas.

Brand Equity

Brand equity for AVACEN Medical is built on three constructs: resources, product differentiation, and global outreach. In terms of resources, the company has a very strong and reputed board of directors including Dr. Gary Pace, Director of ResMed, a market leader in the respiratory device industry with over 30 years of experience in the healthcare industry; Dr. Srinivas Rao, a member of the American College of Neuropharmacology, the American Pain Society, International Association for the Study of Pain, and the Society for Neuroscience; Dr. Judith L. Swain, former Chair of the

Department of Medicine at Stanford University and a Senior Fellow at the Agency for Science, Technology & Research (A*STAR) Singapore; and other members with immense experience in the healthcare and medical device industry.

In addition to the AVACEN 100 being the only OTC product approved in the European and Canadian market for fibromyalgia widespread pain treatment, it is suitable for patients of all ages. All other products available in the market do not provide such a wide range of potential applications that AVACEN 100 offers, which includes wound healing, migraine pain control, stress management, muscle relaxation, and rehabilitation.

In terms of global reach, the company is collaborating with leading institutions and companies such as Apollo Hospitals, in India. In addition, AVACEN Medical has entered into a strategic agreement with CellMark, a Sweden-based company with a presence in more than 120 countries worldwide, to market its product globally. The company is continuously seeking to increase its brand value and is positioned as a unique innovator.

Conclusion

The global healthcare industry is increasing its focus on providing more value-based care delivery by improving patient access to care, patient outcomes, and treatment quality in a cost-effective way. AVACEN Medical—through its first-to-market OTC, drug-free pain relief product, the AVACEN 100—aligns itself with these changing industry dynamics and offers a safe and effective solution with a unique approach to treating fibromyalgia sufferers. It not only aims to treat the widespread pain associated with fibromyalgia, but also to aid in wound healing, migraine pain control, stress management, muscle relaxation, and rehabilitation intended to increase patients' quality of life by significantly improving their functionality and reducing the burden on healthcare providers. The company plans to conduct more efficacy and cost-benefit studies to expand use of its revolutionary device into hospital and medical communities, which will be critical as it continues to establish itself in the European and Canadian fibromyalgia pain management market.

With its strong overall performance, AVACEN Medical has earned Frost & Sullivan's 2017 New Product Innovation Award.

Significance of 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.



Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high-quality products that have a profound impact on the customer.

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

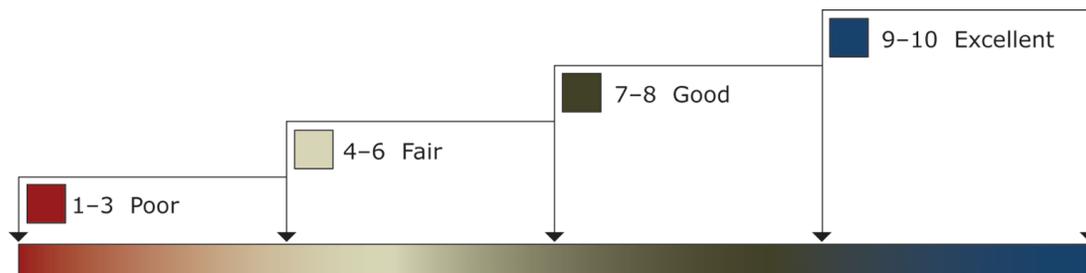
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

Best Practices Award Analysis for AVACEN Medical

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

RATINGS GUIDELINES



The Decision Support Scorecard is organized by New Product Attributes and Customer Impact (i.e., These are the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard.). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, we have chosen to refer to the other key participants as Competitor 2 and Competitor 3.

<i>Measurement of 1-10 (1 = poor; 10 = excellent)</i>			
New Product Innovation	New Product Attributes	Customer Impact	Average Rating
AVACEN Medical	9	9	9
Competitor 2	8	6	7
Competitor 3	6	6	6

New Product Attributes

Criterion 1: Match to Needs

Requirement: Customer needs directly influence and inspire the product’s design and positioning.

Criterion 2: Reliability

Requirement: The product consistently meets or exceeds customer expectations for consistent performance during its entire life cycle.

Criterion 3: Quality

Requirement: Product offers best-in-class quality, with a full complement of features and functionalities.

Criterion 4: Positioning

Requirement: The product serves a unique, unmet need that competitors cannot easily replicate.

Criterion 5: Design

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

Customer Impact

Criterion 1: Price/Performance Value

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

Criterion 2: Customer Purchase Experience

Requirement: Customers feel they are buying the most optimal solution that addresses both their unique needs and their unique constraints.

Criterion 3: Customer Ownership Experience

Requirement: Customers are proud to own the company’s product or service and have a positive experience throughout the life of the product or service.

Criterion 4: Customer Service Experience

Requirement: Customer service is accessible, fast, stress-free, and of high quality.

Criterion 5: Brand Equity

Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.



Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 Monitor, target, and screen	Identify Award recipient candidates from around the globe	<ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies 	Pipeline of candidates who potentially meet all best-practice criteria
2 Perform 360-degree research	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates 	Matrix positioning of all candidates' performance relative to one another
3 Invite thought leadership in best practices	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> • Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps 	Detailed profiles of all ranked candidates
4 Initiate research director review	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> • Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles 	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 Assemble panel of industry experts	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> • Share findings • Strengthen cases for candidate eligibility • Prioritize candidates 	Refined list of prioritized Award candidates
6 Conduct global industry review	Build consensus on Award candidates' eligibility	<ul style="list-style-type: none"> • Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates 	Final list of eligible Award candidates, representing success stories worldwide
7 Perform quality check	Develop official Award consideration materials	<ul style="list-style-type: none"> • Perform final performance benchmarking activities • Write nominations • Perform quality review 	High-quality, accurate, and creative presentation of nominees' successes
8 Reconnect with panel of industry experts	Finalize the selection of the best-practice Award recipient	<ul style="list-style-type: none"> • Review analysis with panel • Build consensus • Select recipient 	Decision on which company performs best against all best-practice criteria
9 Communicate recognition	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> • Present Award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance 	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 Take strategic action	Upon licensing, company is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> • Coordinate media outreach • Design a marketing plan • Assess Award's role in future strategic planning 	Widespread awareness of recipient's Award status among investors, media personnel, and employees

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 participants and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.