## New Product Launches, Approvals, And Acquisitions to Expand Pain Management Devices Portfolio Worldwide

## Ashish Gujrathi

Allied Market Research, Viman Nagar Pune Sainik Nagar, Somnath Nagar, Wadgaon Sheri, Pune.

**Corresponding Author:** Ashish Gujrathi. Allied Market Research, Viman Nagar Pune Sainik Nagar, Somnath Nagar, Wadgaon Sheri, Pune.

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Advancements in technology and the approach of innovation by healthcare companies led to considerable improvements in pain management devices over the past years. From management of chronic pain to reliving post-operative pain, innovative devices have been making their way into the world. Leading device manufacturers have been developing and launching their new products that would relive and manage different kinds of pain. From knee braces to cap-sized neuromodulation devices, new products have been launched to help people improve the quality of their lives. Some of the products are in the development stage, while some have been commercialized and launched. The trend of innovation is expected to bring breakthrough devices in the coming years.

The U.S. Food and Drug Administration (FDA) authority has been scrutinizing the novel devices developed by healthcare companies for pain management and offering approvals following a careful consideration. One of the leading companies in the healthcare sector gained approval for its neurostimulators that can be used for diabetic patients. These devices relieve pain and improve the quality of life for diabetic patients. The FDA also approved the virtual reality-based devices for those indulged in psychological treatment associated with chronic pain. This innovative approach will help in complementing the ongoing medical treatment for people undergoing chronic pain.

Acquisition is also one of the major strategies adopted by market players to expand their product portfolio and raise their stakes. This strategy also helps in strengthening the position in the market as the assets of the companies can be combined to offer integrated, scalable, and reliable solutions for those in need. This will help in increasing the overall revenue and lead toward achieving growth. The market for pain management devices and solutions is expected to grow considerably in the coming years. According to the report published by Allied Market Research, the global pain management devices market is estimated to reach \$5.76 billion by 2028. Following are some of the trends and activities taking place across the world.

Market players adopted the strategy of new product launches to widen its overall product portfolio, raise its market share, and strengthen its position across the international market. They adopted an approach of innovation to launch its new products to relieve pain of different types in individuals. TensCare, one of the leading pain management and relief device providers for transcutaneous electrical nerve stimulation (TENS), launched its new products for different types of pain relief. The company introduced a novel device for lowering down wrinkles and fine lines, Uniglo Muscle Stimulator.

Along with this device, the company launched Mynd, a wearable TENS migraine relief device. This is a long-life and rechargeable device that can be used in 40 adjustable intensity steps for providing effective and comfortable treatment for users. When the device is placed on the forehead, it sends a gentle electric current through the gel electrode pad to the trigeminal nerve. Then the migraine signals are reduced. The company will continue to launch such drug-free pain relief and management and muscle rehabilitation devices through its research and development program. It will utilize the most advanced digital technology for development of innovative products.

The trend of new launches continues with market players realizing the potential in areas such as post-operative pain management. Zynex, Inc., one of the innovative health technology companies operating in pain management, rehabilitation, and patient monitoring, launched knee braces for management of post-operative pain and osteoarthritis (OA). The company realized a knee is the most commonly injured body part, and the issues related to knees are rising across the world. Moreover, OA occurs due to family history, fractures, obesity, and other reasons. In both cases, braces have capability to restrict the wear and tear along with lowering down the pain of impacted joints. In addition, they postpone or lower down the possibility of surgery along with improving mobility of knees.

Zynex's newly-launched post-operative braces are useful after orthopedic surgeries such as ACL/PCL, meniscus repairs, fixing of fracture, and others. Thomas Sandgaard, the Founder, Chairman, and Chief Executive Officer of Zynex, highlighted that the new addition will serve its existing prescribers and diversify its revenue streams by joining more prescribers in the orthopedic area. Not only healthcare technology companies but also teen inventors have been contributing to ease the pain of people through their innovative devices. Teen siblings launched a portable neuromodulation device to ease chronic pain by putting users in a meditative state. The Fluxwear Shift inserts electromagnetic pulses into a user's brain. These pulses synchronize with neurons that resemble with the neurons that put a person in a meditative state. Kamran Ansari, the 16 years old inventor, came up with the device as his sister suffered from pain due to Guillain-Barre syndrome. She tried different pain relief procedures and treatment before turning to neuromodulation. Electric simulation is utilized for changing the nerve activities. However, carrying the heavy neuromodulator devices proved cumbersome. The inventor Kamran decided to develop a device that would allow her to carry it everywhere and utilize whenever needed.

He developed a new device that can be fitted inside a cap. It is capable of delivering low levels of energy with the help of emitters. These emitters develops multidirectional field and raise synchronicity with different areas of brain. This puts a user into a deep meditative state. The effects are repeated with 25 minutes of usage. As his sister began usage of this device in October 2020, she was able to relieve the pain and improved her health conditions by March 2021. She needed to make changes in diet before utilization of this device; however, she no longer needed to make dietary changes with the device. She can attend the school full-time and do all the activities that were restricted before the usage of the device. This device has also been tested on other patients and impact on levels of pain and anxiety were recorded. However, no data has been published yet. The teenage inventor took a help of number of neuropsychologists and neurologists for development of this device. The U.S. Food and Drug Administration (FDA) gave a clearance for the device in Class I. Further development and commercialization are pending for the device, and will be carried out in the coming years.

New products will be launched in the near future as the U.S. FDA provides approvals for different devices and treatment options. Medtronic, one of the leading medical devices companies, received an approval from the U.S. FDA for its Intellis rechargeable neurostimulator and Vanta recharge-free neurostimulator. Both of these devices can be utilized for relieving and management of chronic pain related to diabetic peripheral neuropathy (DPN). These devices are a part of spinal cord stimulation (SCS) product portfolio, and offer multiple programming options such as MRI access, personalized therapy, performance, and others. Moreover, they contain TYRX Neuro Absorbable Antibacterial Envelope that can reduce infection by nearly 60% and stabilizes the placement of the device.

Charlie Covert, the Vice President and General Manager for Pain Therapies for the Neuromodulation Business at Medtronic, outlined that DPN poses a great challenge for diabetic patients and lowers the quality of their lives. The new devices are developed with the proven experience of Medtronic in SCS and expertise in diabetes. They are designed and developed to offer better care as compared to traditional methods to a large number of patients. Many studies have shown that nearly 70% of DPN patients undergoing the SCS treatment reported relief from pain, while only 6% of the DPN patients undergoing conventional treatment reported relief. Moreover, there has been significant improvement in quality of life in patients undergoing SCS treatments. This prompted the company to develop novel devices that can improve the quality of life by relieving pain and eliminating infections in DPN patients.

The U.S. FDA has been approving breakthrough devices to help people suffering from chronic pain improve the quality of their lives. It approved EaseVRx, a virtual reality headset that can be used to relive chronic pain in adults. This device utilizes a technique known as cognitive behavioral therapy. Once an individual wears the headset and turns it on, they will enter the 3D world in which they will learn and gain different information

about pain such as how brain responds to pain, how pain is present in the central nervous system, and what can be done to relieve the pain.



A treatment program consisting of 56 sessions over eight weeks has been designed. The U.S. FDA reported that nearly 66% of participants who used the device stated that they experienced more than 30% reduction in pain. Dr. Beth Darnall, the Director of the Stanford Pain Relief Innovations Lab in California and the Chief Science Adviser and Cocreator of the EaseVRx, highlighted that this is a breakthrough device in terms of pain treatment and conceptualization of pain. This device will not eliminate the medication, but will work alongside the medical treatment. The physician or clinician can determine the course of treatment based on conditions of the patients. One of the licensed psychologists at the University of Kansas Health System, outlined that the devices like these will help in raising the adherence to treatments and self-regulatory techniques. Moreover, they lower down the access barriers for patients who are finding psychologists that offer pain-focused psychotherapy.

Along with approvals and launch of new devices, the trend of acquisition has been arrived. The expansion of existing pain management devices is one of the major reasons behind the adoption of this strategy. Hinge Health, one of the leading healthcare companies, planned to acquire Enso for expansion of its musculoskeletal therapy solution range. Enso reportedly created a non-invasive device that proved to offer clinical relief for nearly 86% of patients in the clinical trials and lower down pain by nearly 56%. This device can be operated with the help of smartphone app. It provides electrical simulation treatment for relaxation of muscles and calming the nerves. This device can be utilized for reducing chronic and acute pain. Nearly 100 medical centers in the U.S. have been utilizing the device.

Hinge Health has a digital platform in which wearable sensors and oneon-one coaching is provided. This platform is used for offering in-home MSK therapy. The digital MSK therapy is developed for reducing back and joint pain along with acute and chronic pain relief and rehabilitation. The acquisition of Enso would expand the product portfolio through addition of its non-invasive device and provide an innovative tool for treatment of MSK pain. The combination of the digital MSK therapy of Hinge Health with a non-invasive high-frequency impulse technology of Enso will open new avenues in the field of pain management. Jeffrey Krauss, M.D. and the Chief Medical Officer at Hinge Health highlighted that Enso's clinically validated pain relief device complements its existing motion sensor technology and extensive clinical team. Through the combination of the solutions of both companies, users can prevent elective surgeries and avoid opioid prescriptions. The strategy of acquisition will also open up new opportunities for the growth for Hinge Health.

More companies have been adopting this strategy to combine their solutions with devices and technologies of other companies and provide enhanced solutions for its customers for chronic pain relief and management. DarioHealth carried out acquisition of Upright Technologies for \$31 million for expanding its product portfolio for chronic pain management. This acquisition will expand the multi-condition platform of DarioHealth and get nearly 90,000 active users of Upright under its tree. Upright aims to prevent and treat MSK conditions through wearable tech, behavioral science, and coaching. DarioHealth plans to offer integrated solutions for chronic pain management in combination with Upright's technology.

Rick Anderson, the President and General Manager of DarioHealth North America, highlighted that the acquisition is expected to make its platform robust and best-in-class. The company can offer front end and back end solutions for its combined community of 150,000 members. Moreover, the combination would offer sensor- and AI-driven behavior changes and coaching to reduce costs for employers, payers, and healthcare providers. He outlined that the acquisition is expected to make a lasting impact on members and provide excellent health outcomes. The technologically-advanced pain management devices and solutions will be integrated and provided for millions of people who are in need to manage and relieve pain.



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