Neuromodulation Product Approved For Treatment Of Spasticity

Codman & Shurtleff, Inc. (Codman), the global neurological device company, has received U.S. Food and Drug Administration (FDA) approval through a PMA supplement for its MEDSTREAM™ Programmable Infusion System, an implantable infusion pump and catheter system used in the treatment of spasticity, a movement disorder often caused by stroke, cerebral palsy, multiple sclerosis or spinal cord injury. The device will be available through a phased roll out in the United States over the next several months.

The MEDSTREAM System delivers a continuous and highly accurate(1) dose of the anti-spasm drug baclofen directly to the spinal canal to relieve the severe spasticity, a condition that affects more than 12 million people worldwide. (2) The new implantable system is equipped with an eight-year battery life even at high flow rates and features the SURESTREAM™ Intraspinal Catheter, a kink-resistant catheter designed to deliver uninterrupted therapy.

The MEDSTREAM System marks Codman's entry into the field of neuromodulation, technology that uses implantable devices to deliver medication or electrical impulses to treat diseases of the central nervous system.

"Neuromodulation is an important area in need of innovations that improve accuracy, reliability and device longevity," said Stan Fisher, MD,* Co-Director, Movement Disorders and Neurorehabilitation Center, Methodist Neurological Institute and Assistant Professor of Neurology, Weill Cornell Medical College.

The MEDSTREAM System, which has already been approved for use in Europe, is the first programmable infusion system to feature a Ceramic Drive System that precisely controls drug dosage. The drive system contains no gears, motors or rotating parts that can wear or stall. Medication is delivered within 10 percent of the programmed flow rate and the device is certified for use in 3-Tesla MRI systems.

Use of the MEDSTREAM System involves the implantation of a pump, about three inches in diameter and about one-inch thick, inside a patient's abdomen. Baclofen is transported from the pump directly to the spinal area with the SURESTREAM Catheter. Clinicians use a computerized wireless control unit to non-invasively program dosing and flow rate for each patient based on his or her specific needs.

"The MEDSTREAM System is an important advancement that may help thousands of patients suffering from spasticity improve function," said P. Laxmin Laxminarain, Worldwide President of Codman. "We are committed to developing products that can make a meaningful difference in people's lives and lessen the global burden of

neurological disease."

Delivery of baclofen with implantable infusion devices has been shown to reduce side effects compared to oral administration of the drug.(3) Infusion therapy is not a cure for spasticity, but may help manage its symptoms. Patients should discuss the risks and benefits of baclofen treatment with infusion devices with their doctors.