

## PAINFREE PUMP—FOR POSTOPERATIVE COMFORT

*The First and the Best Ambulatory Pain Management Device*

Postoperative pain is a common occurrence among all surgical specialties. Unrelieved pain after surgery is unhealthy and can affect the quality of a patient's final result. The ideal goal for relieving postoperative pain should be to reduce or eliminate pain and discomfort with a minimum of side-effects. The **PainFree Pump** by **Sgarlato Laboratories** (Los Gatos, CA), a patented spring-operated, pain management solution, is an innovative approach to pain management and spinal disorders and recovery that focuses on accelerated healing and faster rehabilitation. This portable delivery system is designed to provide continuous infusion of a local anesthetic to the surgical wound site to decrease postoperative pain without limiting a patient's ability to function or return to daily routines. The technology behind this device has been advancing for more than two decades. The PainFree Pump is a refinement and enhancement of Sgarlato's successful Pain Control Infusion Pump (PCIP), which was first introduced in 1996, and its modifications are based on years of physician and patient feedback, independent clinical research, and ongoing R&D efforts.

On this horizon is Sgarlato Labs' new, patented methodology for treatment of acute and chronic lumbar spinal conditions. The "**ICE**" **Infusion Catheter Epidural**, which operates in conjunction with the PainFree Pump, is currently being tested as a treatment for conditions such as radiculopathy, spinal stenosis,

and discogenic lumbar pain, as well as a variety of other low-back disorders. The Infusion Catheter Epidural works by placing a spinal catheter via an interlaminar approach to the affected spinal segment. The catheter is then connected to the PainFree Pump. The medication, which consists of a corticosteroid and normal saline, is then infused at a predetermined rate over course of 72 hours. This medication delivery system ensures a more thorough saturation of the inflamed tissues, resulting in a greater and longer-lasting patient comfort.



Lumbar epidurals have long been the treatment of choice for lower back disorders when they do not respond to conservative measures. Unfortunately, epidurals in this setting are only partially or transiently effective in many patients. Michael Shapiro, MD, CEO of Physician Technologies, Inc., inventor of the Infusion Catheter Epidural, believes one of the main reasons for failure of traditional epidurals is because the rich

venous plexus in the epidural space may re-absorb the medications systemically before they have a full opportunity to work. This is evidenced by the fact that patients frequently exhibit systemic adverse reactions from corticosteroids administered in the epidural space. Dr. Shapiro relates that often times when a contrast dye is given before injecting medication to verify correct placement of the spinal needle, follow-up fluoroscopic x-rays taken within five minutes reveal that the dye has been completely re-absorbed and is no longer

visible on the x-rays. Dr. Shapiro believes the same re-absorption process must occur with the medication as well, explaining why many patients only get partial or short-temporary relief. Early clinical trials with the Infusion Catheter Epidural have been very favorable and have shown it to be well tolerated, with no known complications or adverse reactions to date. The Infusion Catheter Epidural should be available for commercialization in the next few months.

The PainFree Pump is the most reliable and accurate pump on the market. Using a unique, patented technology, the PainFree Pump's spring-operated syringe allows consistent and accurate pressure to force medication to the unique flow restrictor, which regulates the amount of medication that passes into the catheter. The tamper-resistant design and flow restrictor prevent excess drug delivery and rate manipulation. The physician chooses where to place the catheter (near a nerve, nerve bundle, intra-articular, subcutaneous, or subfascia), the medication (e.g. Bupivacaine HCl, Lidocaine HCl, or Ropivacaine HCl), flow rate, and time of therapy. Customizable application options include 100-mL or 200-mL pumps; 1-mL, 2-mL, or 4-mL/hour flow regulators; and multiple catheter choices (20 gauge, 3 port and 20 gauge, 5 port) and multi-site "Y" connector. Depending on the volume and flow rate chosen, 1-4 days of medication can be directed

to the pain site. The catheter is held comfortably and securely in place. A carrying pouch included in the kit can be attached to the patient's clothing. Once the physician fills the pump, chooses a desired flow rate, and inserts the catheter, the PainFree Pump does all the work. The lightweight and compact design encourages patient compliance

The main difference between the PainFree Pump and other pumps on the market is the fundamental spring-operated system. Other pumps use a balloon or vacuum system that has a higher percentage of faulting. The PainFree Pump is not temperature-dependent for flow rate accuracy and there are calibrations on the outside of the pump which indicate how much medication has been infused. The infection rate for the PainFree Pump is less than 1%, and there is information available showing the anti-microbial effects of Bupivacaine. The pump is made of a hard polycarbonate substance used to keep the medication stable and protected from harm, unlike balloon-type pumps that can puncture. The PainFree pump is *not* a patient-controlled device, and is not designed for rapid infusion of medications or for patients with a history of allergic reactions to local anesthetics. The system is also functionally latex-free to lessen the chance of any allergic reaction.

The PainFree Pump is a low-cost alternative to other more costly forms of pain treatment. A survey

of physicians using the PainFree Pump shows the greatest benefit is the decreased time the patient spends in the post-op recovery unit (PACU) where nursing time and care are at a premium. The PACU time saved may be 50%, depending on a particular patient's pain level. The savings continue once the patient leaves the recovery room, limiting or reducing nursing care and potentially expensive clinician intervention. Discharge from the hospital could come 1-2 days earlier with enhanced pain management. There is also the cost savings of the narcotics compared to using the PainFree Pump. Insurance billing is available.

Founded in 1986 by Dr. Thomas E. Sgarlato, Sgarlato Labs, Inc.—the leader in portable infusion pain management—invents, designs, manufactures, and markets medical devices and innovative therapeutic products for surgical use. 

For more information concerning PainFree Pump and other Sgarlato Labs products, call 1-800-421-5303; e-mail to [sales@sgarlatolabs.com](mailto:sales@sgarlatolabs.com); contact a Sgarlato representative at NASS, booth #1406; or visit the company's Web site at [www.sgarlatolabs.com](http://www.sgarlatolabs.com).