



Medtronic

1

Drug Delivery Therapy

PATIENT STORIES



Imagine the Possibilities of Life with Less Pain

For David, it's going to the gym for a good workout and then returning home to play with his children. For Julie, it's being an active mom. And for Phil, it's getting a good night's sleep on a regular basis.

They all have a brighter outlook on life thanks to Medtronic intrathecal drug delivery therapy.

Take Julie, for example. She was in excruciating, uncontrolled pain because of a stress fracture that did not heal properly. Multiple medications, surgeries, and neurostimulation therapy failed to provide relief. Today, Julie feels good again. "When I compare the way I used to feel to how I feel now, it is . . . like heaven!"

Likewise, drug delivery therapy has helped David and Phil manage their pain. "I couldn't believe the relief," Phil said. David said, "Because of the pump I was able to interact with my children and to complete my career to retirement. It has given me a life."

Medtronic drug delivery therapy has helped thousands of people worldwide live more satisfying and meaningful lives. It may also help you.

Shown on the cover are two people who have rejoined their life with the help of drug delivery therapy.

Rob has been receiving drug delivery therapy since July of 2005.

Caroline has been receiving drug delivery therapy since October of 2001.

David's Story

His entire life, David had a strong activity and work ethic. An avid distance runner, he regularly logged 30 to 50 miles per week. In his professional life he was the principal of a special education school for children with disabilities.

Then, one morning his life changed. "I woke up on January 13, 1983, with excruciating back pain," David recalls. "I crawled to the car and was taken to the emergency room. I was hospitalized and diagnosed with a disc herniation at three levels. I had a laminectomy and a posterior fusion."

Despite the surgery, David's pain in his lower back and left leg was relentless. Any movement—including bending backward or forward—sent a shock of electricity down his back to his toes and took his breath away. He continued to work but gave up all exercise. As a result, he became depressed.

"It was very hard on my family," David says. "But I never felt hopeless because I knew my doctor was determined to help me."

David tried every treatment option available to him, including medications that did not relieve the pain and made him feel sleepy. In 1988, he tried neurostimulation therapy, which interrupts pain signals to the brain with mild electrical impulses delivered to the area near the spine, but the pain was too widespread for the device that was available at that time.

"My wife and I desperately wanted to adopt children," he explains. "And I knew that to be considered as an adoptive parent I had to be well. That was my motivation."

REJOIN
your life.

Learning About Drug Delivery Therapy

David's physician attended a conference where he learned about the Medtronic drug pump. The pump delivers pain medication to the intrathecal space surrounding the spinal cord. The system consists of a pump and catheter that are surgically implanted. He thought David would be a good candidate and referred him to the appropriate specialist.

David underwent a screening trial at a hospital where a test dose of medication was administered to the intrathecal space surrounding his spinal cord. If it relieved his pain, he could proceed with the implant surgery. "During the trial I felt great relief," says David. "A total calming down of the severe pain. I still had some discomfort, but not the blinding electrical shock I was used to. I couldn't wait for the surgery!"

David had the pump surgically implanted in the early nineties. While he had no complications, there are risks associated with the procedure. The most frequently reported problems following drug infusion system implant surgery include infection, spinal fluid leak, pump inversion, skin erosion, drug side effects, loss of therapy effect, and therapy which did not meet the patient's expectations. For a complete list of adverse events which have been associated with the therapy please refer to the brief summary at the end of this brochure.

It took David's doctor almost a year to adjust his dosage to the optimal setting to control his pain. "During that time I often felt nauseous, but it was still preferable to the pain." David has had his pump replaced three times because the natural life of the pump batteries had expired.

Today, he continues to experience pain relief with drug delivery therapy and is back to exercising. "My average pain score is a 3 out of 10. I go to the gym daily and work out for an hour and a half."

Best of all, David and his wife were able to realize their dream of adopting two children from Korea. "Because of the pump I was able to interact with my children and to complete my career to retirement. It has given me a life," David says.



David
drug delivery recipient

"Because of the pump I was able to interact with my children and to complete my career to retirement. It has given me a life."

-David

REJOIN
your life.

Julie's Story

On a beautiful day in 1995, Julie decided to extend her usual four-mile walk to six miles. The next day, her foot hurt. A nurse accustomed to spending time on her feet, she knew something was wrong when the pain did not subside after a few days.

"My doctor thought it was a stress fracture and had me wear a hard plastic boot to support the foot for a number of weeks, but it did not heal," Julie remembers. After two years of pain, Julie underwent surgery that revealed a ruptured joint in her left foot at the site of the stress fracture. The rupture was repaired but the pain persisted.

"I had such pain that I couldn't walk or sleep. I became depressed," says Julie.

A podiatrist diagnosed Julie with complex regional pain syndrome and tried addressing it with neurostimulation therapy. Neurostimulation therapy uses a small electronic system placed under the skin. The therapy interrupts pain signals to the brain with mild electrical impulses delivered to the area near the spine. When the treatment did not sufficiently control the pain, she underwent further surgery.

"The pain was terrible," Julie says. "I tried every type of medication without success. I cried myself to sleep. I became desperate and feared I would lose my mind from the pain."

Learning About Drug Delivery Therapy

Julie traveled from her hometown to Chicago to see an anesthesiologist specializing in pain. She underwent a screening test to determine if she was a candidate for drug delivery therapy. The drug pump delivers pain medication to the intrathecal space surrounding the spinal cord. The system includes a pump and catheter that are surgically placed under the skin.

"During the trial I experienced a 60 percent reduction in pain. I was very hopeful," she recalls.

In August 1999, Julie had the pump implanted. "Everyone commented on how happy I was. My dream had been to get back to horseback riding and I was able to do that and also gardening," she says.

In 2007, Julie received a pump that could hold more medication. In the weeks after the procedure she developed an infection, which required surgery to move the pump to a different location. Although Julie did experience an infection, she did not experience any other possible complications. The most frequently reported problems following drug infusion system implant surgery include infection, spinal fluid leak, pump inversion, skin erosion, drug side effects, loss of therapy effect, and therapy which did not meet the patient's expectations. For a complete list of adverse events which have been associated with the therapy please refer to the brief summary at the end of this brochure.

Today, Julie is back to being an active mother. "When I compare the way I used to feel to how I feel now, it is like heaven! I feel so good that I have vowed to never complain about pain again," says Julie.

REJOIN
your life.



Julie
drug delivery recipient

“When I compare the way I used to feel to how I feel now, it is like heaven! I feel so good that I have vowed to never complain about pain again.”

–Julie

Phil's Story

Phil could never have imagined at age 18 that an accident at a party would lead to chronic pain that he would endure for years. While in New Orleans with friends celebrating Mardi Gras, he decided to leave a party by way of the balcony.

“It was crowded at the party and going over the balcony seemed the easiest exit. It didn't look too far down to the street,” Phil recalls. “I was a very coordinated athlete and so I stepped over the railing and dropped to the street below. Unfortunately, I landed in an unusual position with my heel hitting the rounded curb and fracturing the bone.”

An infection developed in his heel that took four years and 12 surgeries to clear. Part of his heel was removed and a graft was placed. Phil used crutches and sometimes a cane to walk.

Throughout his 20s, Phil managed the pain in his heel with mild pain medications and an intense exercise routine. But as he aged, he needed stronger medication that produced intolerable side effects. In his late 30s, Phil felt new pain that traveled down his legs. It was diagnosed as degenerative arthritis, likely tied to a back injury sustained in the fall from the balcony.

“All I could do was lie down,” Phil says. “I reached a point where I didn't care about anything but pain relief. I would cry at the doctor's office. They were tears of fear. I didn't know where my life was going.”

REJOIN
your life.

Learning About Drug Delivery Therapy

One day Phil's sister shared an article she had read about the entertainer Jerry Lewis and the pain relief he experienced from neurostimulation, a therapy that interrupts pain signals to the brain with mild electrical impulses delivered to the area near the spine.

He brought the article to his doctor, who thought Phil might be a better candidate for intrathecal drug delivery from Medtronic. Drug delivery is designed to manage pain by delivering pain medication to the intrathecal space surrounding the spinal cord. Because this therapy delivers pain medication directly to the receptors in the spinal cord, smaller doses of medication are required to gain relief than oral medications. The system consists of a pump and catheter. Both are surgically implanted under the skin.

In June 2004, at age 51, Phil had the pump implanted. While he had no complications, there are risks associated with the procedure. The most frequently reported problems following drug infusion system implant surgery include infection, spinal fluid leak, pump inversion, skin erosion, drug side effects, loss of therapy effect, and therapy which did not meet the patient's expectations. For a complete list of adverse events which have been associated with the therapy please refer to the brief summary at the end of this brochure.

After surgery Phil was in pain, but "the pain was from the surgery itself, not the pump," he explains. "Once that subsided, I couldn't believe the relief. I was able to sleep again. My pain score went from a 9 down to a 3. And when I was sleeping or sitting, I had no pain at all. I was a new person."



Phil
drug delivery recipient

*"And when I was sleeping or sitting,
I had no pain at all. I was a new person."*

-Phil

REJOIN
your life.

SYNCHROMED® II DRUG INFUSION SYSTEM BRIEF SUMMARY:

Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure. Indications: US: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity; chronic intravascular infusion of flouxidrine (FUDR) or methotrexate for the treatment of primary or metastatic cancer. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling. **Contraindications:** When infection is present; when the pump cannot be implanted 2.5 cm or less from the surface of the skin; when body size is not sufficient to accept pump bulk and weight; when contraindications exist relating to the drug; drugs with preservatives. Do not use the Personal Therapy Manager accessory to administer opioid to opioid-naïve patients or to administer ziconotide. **Warnings: Comply with all product instructions for initial preparation and filling, implantation, programming, refilling, and injecting into the catheter access port (CAP) of the pump. Failure to comply with all instructions can lead to technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant or fatal drug under- or overdose.** Refer to the appropriate drug labeling for specific under- or overdose symptoms and methods of management. Avoid using short-wave (SW) diathermy within 30 cm of the pump or catheter. Diathermy may produce significant temperature rises in the area of the pump and continue to heat the tissue in a localized area. If overheated, the pump may over infuse the drug, potentially causing a drug overdose. Effects of other types of diathermy (microwave, ultrasonic, etc) on the pump are unknown. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal therapy carefully for any new neurological signs or symptoms. For intraspinal therapy, use only preservative-free sterile solution indicated for intraspinal use. Use only Medtronic components indicated for use with this system. Failure to firmly secure connections can allow drug or cerebrospinal fluid (CSF) leakage into tissue and result in tissue damage or inadequate therapy. A postoperative priming bolus should not be programmed if the pump is a replacement and the catheter has not been aspirated. Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures. Physicians must be familiar with the drug stability information in the technical manual and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion. Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system. Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention. Instruct patients to notify their clinician of travel plans, to return for refills at prescribed times, avoid activities such as strenuous exercise or contact sports that jar, impact, twist, or stretch the body, to always carry their Medtronic device identification card, to avoid manipulating the pump through the skin, and to notify healthcare professionals of the implanted pump before medical tests/procedures. Patients must consult their physician before engaging in activities involving pressure or temperature changes (e.g., scuba diving, saunas, hot tubs, hyperbaric chambers, flights, skydiving, etc) Inform patients that pump has an Elective Replacement Indicator (ERI) that sounds when the pump is nearing its end of service. When the alarm sounds, patients must contact their doctor to schedule pump replacement. **Precautions:** The pump is ethylene oxide sterilized. Do not use if the product or package is damaged, the sterile seal is broken, or the "Use By" date has expired. Do not reuse or resterilize the pump; it is intended for "single use only." Do not expose the pump to temperatures above 43°C or below 5°C. Consider use of peri- and post-operative antibiotics for pump implantation, for any subsequent surgical procedure, or if infection is present. For patients prone to CSF leaks, clinicians should consider special procedures, such as a blood patch. Follow instructions for emptying and filling the pump during a replacement or revisions that require removal of the pump from the pocket. Explain the pump postmortem if incineration is planned (to avoid explosion), or if local environmental regulations mandate removal. Return explanted devices to Medtronic for analysis and safe disposal. Do not implant a pump dropped onto a hard surface or showing signs of damage. Implant the pump less than 2.5 cm from the surface of the skin. Ensure pump ports will be easy to access after implant; that the catheter is not kinked and secured well away from pump ports before suturing. Keep the implant site clean, dry, and protected from pressure or irritation. If therapy is discontinued for an extended period of time, fill the reservoir with preservative-free saline in intraspinal applications or appropriate heparinized solution (if not contraindicated) in vascular applications. The magnetic field or telemetry signals produced by the programmer may cause sensing problems and inappropriate device responses with an implantable pacemaker and/or defibrillator. Electromagnetic interference (EMI) is an energy field generated by equipment found in the home, work, medical, or public environments. Most EMI normally encountered will not affect the operation of the pump. Exceptions include: injury resulting from heating of the pump which can damage surrounding tissue (diathermy, MRI), system damage which can require surgical replacement or result in loss/change in symptom control (defibrillation, electrocautery, high-output ultrasonics, radiation therapy), and operational changes to the pump causing the motor to stop, loss of therapy, return of underlying symptoms, and require confirmation of pump function (diathermy, high magnetic field devices, hyperbaric/hypobaric conditions, magnetic resonance imaging (MRI)). MRI will temporarily stop the pump motor's rotor due to the magnetic field of the MRI scanner and surgical drug infusion during MRI exposure which will cause the pump alarm to sound. The pump should resume normal operation upon termination of MRI exposure. Prior to MRI, the physician should determine if the patient can safely be deprived of drug delivery. If not, alternative delivery methods for the drug can be utilized during the MRI scan. Prior to scheduling an MRI scan and upon its completion, pump status should be confirmed. **Adverse Events:** Include, but are not limited to: cessation of therapy due to end of device service life or component failure, change in flow performance due to component failure, inability to program the device due to programmer failure, CAP component failure; inaccessible refill port due to inverted pump, pocket seroma, hematoma, erosion, infection, post-lumbar puncture (spinal headache), CSF leak, radiculitis, arachnoiditis, bleeding, spinal cord damage, meningitis (intrathecal applications), anesthesia complications, damage to the pump, catheter and catheter access system due to improper handling and filling before, during, or after implantation; change in catheter performance due to catheter kinking, disconnection, leakage, breakage, occlusion, dislodgement, migration, or catheter fibrosis; body rejection phenomena, surgical replacement of pump or catheter due to complications; local and systemic drug toxicity and related side effects, complications due to use of unapproved drugs and/or not using drugs in accordance with drug labeling, or inflammatory mass at the tip of the catheter. **USA Rx Only January 2008**

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure.

Indication for Use - Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings:** Defibrillation, diathermy, electrocautery, MRI, RF ablation, & therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. Electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. **Precautions:** The safety and effectiveness of this therapy has not been established for: pediatric use, pregnancy, unborn fetus, or delivery. Follow programming guidelines & precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, & other activities may cause shocking/jolting. **Adverse Events:** Undesirable change in stimulation; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, & surgical risks.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. **Rx Only.** November, 2007.

