Real Chronic Pain Relief with Medtronic Pain Therapies

*Neurostimulation helps manage chronic pain and Medtronic offers the only neurostimulators* approved for MRI head scans.

The following story captures one individual’s experience with a Medtronic neurostimulation system. Results vary; not every individual will receive the same results. Side effects can occur. For complete prescribing information, please refer to the last page of this newsletter.

While taking a walk over her lunch hour at work one day, Mary experienced excruciating pain in her back. At her doctor appointment, an MRI revealed multiple disc herniation in the L1 through L5/S1 region of her back and a nerve impingement.

“I had so much pain I didn’t know what to do,” Mary recalls.

Her doctor prescribed an epidural and pain medication, but those treatments did not provide relief. After more discussion with her neurosurgeon, it was decided that Mary needed surgery on her back.

“Initially, the surgery seemed to help,” Mary says. “But the pain came back full force in my lower back and radiated down into my left leg.” A year after the procedure, Mary was in severe pain and taking Vicodin and using a fentanyl patch to control it.

“I had no life and I felt hopeless. I couldn’t leave the house, work, or participate in family activities,” she remembers. “I tried to grin and bear it, but it was just too much.”

*Except Itrel 3.

---

Welcome

The Living Well Program reaches thousands of people who find relief from chronic pain with Medtronic Pain Therapies.

We value your feedback. Please share your comments, recommendations, and ideas for future issues.

Thank you for your continued interest in The Living Well Program … and thanks for being green with us!
Life with Neurostimulation Therapy

Mary's pain management physician suggested she consider neurostimulation therapy. After a successful screening test, she had the device placed in August 2009.

“I am doing so much better with the neurostimulator,” Mary says. “Before, I felt like I was in hibernation because I was in so much pain. Now, I can garden outdoors and clean my house by myself. I'm enjoying spending time with my grandchildren and having them for sleepovers—something I wasn’t up to before receiving the neurostimulator.”

MRI and Medtronic Pain Therapies

Recently, Mary started experiencing seizures due to a condition unrelated to her neurostimulator. She had no history of seizures and her doctor wanted an MRI of her head to rule out a brain tumor. Because Medtronic devices have conditional approval for some types of MRIs of the head, Mary’s doctor was able to perform an MRI head scan.

Mary received a MRI head scan and it showed she did not have a brain tumor. Today, she is able to attend to her garden and spend time with her family.

MRI Questions?

Patients can contact Medtronic Patient Services at 1-800-510-6735 from 8:00 am–5:00 pm Monday through Friday.

For specific instructions and labeling, clinicians should refer to professional.medtronic.com/mri or call Medtronic Technical Services at 1-800-328-0810.

What’s New in Pain Management

Individual Difference in Pain Responses

Why do some people feel more pain, and others respond more favorably to certain treatments? Roger Fillingim, a professor with the University of Florida College of Dentistry, addressed this issue at a recent session of the American Pain Society sponsored by the American Pain Foundation.

Following are some of the pain experience variabilities Dr. Fillingim shared:

- There are major individual differences in responses to pain treatment (i.e., patients may need different doses of medication for pain relief).
- Individual differences reflect the complexity of pain processing.
- Genetic and nongenetic factors contribute to individual differences. Some types of pain may be hereditary. There is a need to understand how genetics combine with other factors to affect pain.

Dr. Fillingim cautioned that genetics alone may not explain pain, and encouraged clinicians to study social and psychological circumstances to determine response to pain and pain treatments. For more information, read the full article.

Help for Pain Through ACPA

If you know someone who is living with chronic pain, or if you have found relief but some degree of pain persists, the American Chronic Pain Association (ACPA) may be able to help.

Founded in 1980, the ACPA provides resources for people with pain and the clinicians who treat them. The ACPA is active in the US, Canada, Great Britain, and many other countries.

“We know that living with chronic pain is challenging,” says Penney Cowan, executive director and ACPA founder. “But we also know that there is more to chronic pain than the pain. At the ACPA, we understand the many challenges and obstacles that each person with pain faces.”

To help address those challenges and obstacles, the ACPA provides a variety of resources, including:

- Fact sheets
- Reading lists
- Professional association information
- Question-and-answer forum
- Quarterly newsletter
- Local ACPA support groups
- Physician finder
- Consumer Guide to Pain Medication and Treatment
- Pain Log
- Five minute relaxation
- Fibromyalgia Log
- Quality of Life Scale
- Consumer Guide to Low Back Pain

To connect people to resources, the ACPA relies on its staff, advisors and board members located across the country, and local peer support group leaders. To learn more about the ACPA, visit www.theacpa.org or call 800-533-3231.

Did you Know?

Head scans account for 24% of MRIs.1 If you need an MRI of your head, you can have one if you have a Medtronic neurostimulation system.* Only Medtronic neurostimulation systems for chronic pain have conditional approval for MRI head scans.

*Excludes Itrel® 3, Matrixx® and X-trel™ neurostimulation systems.
Important Safety Information

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® (baclofen injection) for the management of severe spasticity; chronic intravascular infusion of fluorouracil (5-FU) 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: Infection; implant depth greater than 2.5 cm below skin; insufficient body size; spinal anomalies; drugs with preservatives, drug contraindications, drug formulations with pH <3, use of catheter access port (CAP) kit for refills or of refill kit for catheter access, blood sampling through CAP in vascular applications, use of Personal Therapy Manager to administer opioid to opioid-naive patients or to administer ziconotide.

Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring repair or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose. Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, screening procedures and underdose and overdose symptoms and methods of management. Physicians must be familiar with the drug stability information in the product technical manuals 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. 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 intrathecal therapy carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation.

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, including prodromal signs and symptoms of inflammatory mass. Failure to recognize signs and symptoms and seek appropriate medical intervention can result in serious injury or death. Instruct patients to notify their healthcare professionals of the implanted pump before medical tests/procedures, to return for refills at prescribed times, to carry their Medtronic device identification card, to avoid manipulating the pump through the skin, to consult with their clinician if the pump alarms and before traveling or engaging in activities that can stress the infusion system or involve pressure or temperature changes. Strong sources of electromagnetic interference (EMI), such as short wave (RF) diathermy and MRI, can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. Avoid using shortwave (RF) diathermy within 30 cm of the pump or catheter. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. Drug infusion is suspended during MRI; for patients who can not safely tolerate suspension, use alternative drug delivery method during MRI. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively. Confirm pump status before and after MRI. Reference product labeling for information on sources of EMI, effects on patient and system, and steps to reduce risks from EMI.

Precautions: Monitor patients after device or catheter replacement for signs of underdose/overdose. Infuse preservative-free (intraspinal) saline or, for vascular applications, infuse heparinized solutions therapy at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed® II pump may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator).

Adverse Events: Include, but are not limited to, spinal/vascular procedure risks; infection; bleeding; tissue damage, damage to the system or loss of, or change in, therapy that may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose, due to end of device service life, failure of the catheter, pump or other system component, pump inversion, technical/programming errors, or improper use, including use of non-indicated formulations and/or not using drugs or system in accordance with labeling; pocket seroma, hematoma, erosion, infection; post-lumbar puncture (spinal headache), CSF leak and rare central nervous system pressure-related problems; hygroma, radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; potential serious adverse effects from catheter fragments in intrathecal space, including potential to compromise antibiotic effectiveness for CSF infection; anesthesia complications; body rejection phenomena; local and systemic drug toxicity and related side effects; potential serious adverse effects from catheter placement in intravascular applications.

USA Rx Only Rev 1009

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—excluding 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/tingling. Adverse Events: Undesirable change in stimulation; hematoma, epidural hemmorhage, 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. USA Rx Only Rev 0209