Medtronic ITB™ Therapy Fact Sheet

What is Medtronic ITB™ Therapy?
Medtronic ITB Therapy (Intrathecal Baclofen Therapy) is a treatment for individuals with severe spasticity — tight, stiff muscles which can be a symptom of cerebral palsy, multiple sclerosis, brain injury, spinal cord injury, or stroke.

How does ITB Therapy work?
ITB Therapy delivers a medication called Lioresal Intrathecal (baclofen injection) directly to the intrathecal space where fluid flows around the spinal cord. The medication is administered in small doses using the Medtronic SynchroMed® programmable pump. The pump is surgically placed under the skin of the abdomen and connected to a thin tube called a catheter. Once in place, the pump and catheter deliver Lioresal Intrathecal directly to the spinal fluid where it is most effective.

How is the Medtronic SynchroMed programmable pump controlled and refilled?
SynchroMed is the only surgically placed drug infusion system that can be programmed from outside the body. When necessary, a clinician uses a computer-like external programmer to adjust the drug dose and/or infusion rate. This ensures that the most effective amount of Lioresal Intrathecal needed to reduce the spasticity is received. The programming is usually done every 2-3 months when the pump is refilled. To refill the pump, the clinician injects Lioresal Intrathecal through the skin into the pump’s drug reservoir.

Why is ITB Therapy effective?
Delivery makes the difference with ITB Therapy. Because a small amount of medication is delivered directly to the spinal fluid, spasticity can be significantly decreased while possible side effects that often accompany oral medications may be reduced.

Who is a candidate for ITB Therapy?
An individual with severe spasticity who experienced intolerable side effects from oral medications and/or found other therapies ineffective may be a candidate for ITB Therapy. A screening test determines if ITB Therapy may work for an individual. During this test, a health care professional injects a test dose of Lioresal Intrathecal into the fluid around the spinal cord. If the spasticity is significantly reduced, the person may be considered a candidate for ITB Therapy. In clinical studies, ITB Therapy reduced spasticity in 97 percent of people with severe spasticity due to multiple sclerosis and spinal cord injury, and in 86 percent of people with severe spasticity due to cerebral palsy or brain injury.

Is ITB Therapy a proven treatment?
ITB Therapy is a U.S. Food and Drug Administration approved treatment for severe spasticity. Thousands of people receive ITB Therapy to reduce their spasticity. In studies, people have reported that ITB Therapy helped them be more independent, allowing them to feed or dress themselves, sit more comfortably, or transfer more easily. Caregivers also reported that care is easier with ITB Therapy.
Are there any potential side effects associated with ITB Therapy?
In clinical trials, Lioresal Intrathecal (baclofen injection: 10 mg/5mL, 10 mg/20 mL, 0.05 mg/1 mL) was shown to reduce severe spasticity. Results vary; not every individual will receive the same benefits. Possible side effects may include loose muscles, sleepiness, upset stomach, vomiting, headaches, and dizziness. The most common device-related complications reported involve catheter kinks, dislodgment, and breaks. Overdose, although rare, may lead to respiratory depression, loss of consciousness, reversible coma, and in extreme cases, may be life-threatening. However, almost all patients who experienced adverse events in the clinical studies continued with the therapy. Also, as with any surgical procedure, complications can occur after the pump is placed. Since the pump and catheter are placed beneath the skin, infections can develop and are generally related to the healing of the surgical incision, not long-term use of ITB Therapy. Please refer to the enclosed Lioresal Intrathecal package insert and SynchroMed infusion system brief summary for complete prescribing information.

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For more information about ITB Therapy, visit our Web site at www.spasticity.com.

Rx only.

References:
1. Controlled clinical studies on file, Medtronic, Inc.