Twin Cities Pain Clinic

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Patient Informed Consent for Intrathecal Pump Therapy

I, _____, have been informed of the following:

- The goals, benefits, and risks of the intrathecal pump infusion system.
- Alternative methods of treatment for chronic pain.
- How intrathecal medication infusion works to control pain and expectations for relief of pain.
- The surgical implant procedure for the SynchroMed II pump and catheter.
- My role and responsibilities during long-term intrathecal medication therapy with the pump.
- Possible consequences and complications of medication therapy via the SynchroMed II Infusion System.
- Short-term and long-term precautions I must take when implanted with the SynchroMed II Infusion System.

I agree to observe these short-term and long-term precautions:

- Avoid physical activities, which may damage the implant site or device, and restrict my activities to reduce catheter movement for six to eight weeks post-implant per my doctor's orders.
- Schedule appointments for pump refills on a regular basis. This will be determined by the amount of medication used but is generally at 1-6 month intervals.
- Carry my SynchroMed II Identification and Emergency cards with me at all times. These cards will identify me as a recipient of the SynchroMed II infusion system in the event of an emergency.
- Inform my family or significant others of the emergency cards and procedures.

I will inform my provider of the following:

- Adverse side effects of the medication.
- Pain, swelling, or drainage at the incision site. These symptoms may indicate infection.
- Unusual changes in my pain patterns.
- Future travel plans. Referrals and arrangements may need to be made for out of town refills and troubleshooting.
- Inform other physicians I am seeing about this medication program and the pump.

- Call my physician upon hearing any pump alarm. The alarm may mean that the pump is not delivering the drug or will stop delivering the drug in the near future (e/g., the pump needs to be refilled or the pump should be replaced.)

I understand and agree that:

- Intrathecal medication therapy may reduce but not cure or eliminate my pain. Successful therapy generally means reduction in pain, as well as improvements in my ability to function. I may need to be involved in additional therapies, such as physical therapy.

- Intrathecal medication delivery via the SynchroMed II Infusion System will not eliminate the primary source of my pain or "cure" the disease that causes my pain.

- Intrathecal medication delivery via the SynchroMed II Infusion System will not solve my personal and family problems. Because chronic pain may have adversely affected my life and my relationships with others, my physician may recommend counseling or support groups to help me cope with anxiety, depression, and other effects of chronic pain. The goal of this counseling is to provide the greatest opportunity to return to being as active and functional as possible.

- I have been selected as a candidate for intrathecal medication delivery via the SynchroMed II Infusion System because alternative therapies, such as narcotic drugs and surgery, have not worked to control my pain.

- There will be a transition phase after the pump is implanted. I will have other medications gradually reduced so that the appropriate dose levels of the intrathecal drug can be determined. I may not have maximum pain relief during this transition. It is important to work with my physician during this time so that my body can get the maximum benefit of this type of pain medication. This may take weeks to months.

- The implantation of the SynchroMed II Infusion System is associated with certain risks. Any complication that can occur with surgery and anesthesia is possible. In addition, there are risks unique to the implantation of the SynchroMed II. They include but are not limited to infection, accumulation of fluid or blood in the pump pocket site, spinal hygromas, and cerebrospinal fluid leakage through the incision site, spinal headaches, pump pocket erosion, or wound re-opening. Patients usually experience pain and tenderness in the incision sites until healing occurs.

- The FDA has approved certain medications and concentrations that are labeled for the use with the SynchroMed II Infusion system. The approved medications are Preservative-free Morphine Sulfate with a maximum concentration of 20 mg/ml; Preservative-free Baclofen injection with a maximum concentration of 2 mg/ml; Preservative –free Prialt with a maximum concentration of 100 mcg/ml; and lastly Preservative-free floxurideine or methotrexate for treatment of primary or metastatic cancer. Other medications that are NOT approved by the FDA may be used in the pump for your treatment plan. Examples of these medications are Preservative-Free Dilaudid (hydromorphone) or Fentanyl citrate. Please note that although unlikely the use of unapproved drug formulations can increase the risk of pump motor stall due to corrosion in the SynchroMed infusion systems. The use of unapproved drugs or fluids can result in increased risks to the patient and permanent damage to the pump.

- Using alcohol or mood altering drugs while receiving this type of medication may cause serious side effects.

- Under Minnesota State Law it is illegal to operate a motor vehicle while taking schedule II opioids.

- I will avoid use of pain medications other than those prescribed by my Twin Cities Pain Clinic provider.

- Avoid certain medical procedures/devices, unless approved by a physician that may affect the SynchroMed II Infusion system, such as diathermy, therapeutic hypothermia, high-output ultrasonic devices/lithotripsy, radiation therapy, or hyperbaric chamber treatment.

System or procedural complications with the SynchroMed II Infusion System include, but are not limited to:

- Dislodgement, kinking, or breaking of the intrathecal catheter.
- Pump inversion (pump "flips").
- Programming/refill errors.
- Pump pocket problems.
- Problems with the pump itself.
- Inability to withdraw or inject into the catheter access port.
- Development of an inflammatory mass.
- Pump stalls or corrosion to the pump with the use of FDA unapproved medications.

The following prodromal or warning signs and/or symptoms may occur before the onset of more severe neurological impairment:

- Change in character, quality, or intensity of pain.
- New radicular pain, especially at or near the dermatomal level of the catheter tip.
- Frequent or large escalations of the daily drug or dose are required to maintain the analgesic effect.
- Dose escalations may alleviate the patient's increasing pain only temporarily.

All patients on intrathecal opioid therapy should be monitored carefully at each visit for any new neurological signs or symptoms, including:

New or different sensory symptoms (e.g., numbness, tingling, burning, hyperesthesia, or hyperalgesia).

New, occasional, or intermittent bowel and/or bladder sphincter dysfunction.

New motor weakness, change in gait, and/or difficulty walking.

Any neurological symptom or sign that differs from baseline (e/g/, reflex changes).

In patients with new neurological signs and/or symptoms, consider neurological consultation and the prompt performance of imaging procedure (ex. MRI) to confirm or rule-out the diagnosis of an inflammatory mass.

Administration of intrathecal medication has been associated with certain side effects and/or adverse effects, which include but are not limited to itching, urinary retention, constipation, nausea, vomiting, dizziness, anxiety, depression, edema, and myoclonus. An overdose of medication is also possible. It may be recognized as malaise, anxiety, increased pain, headache, myalgia, backache, insomnia, dehydration, and fever.

Increased physical activity (made possible by the therapy) may cause tenderness and muscle weakness. A course of physical therapy may be prescribed to build muscle strength and reduce muscle and joint pain.

The implantable pump is powered by a battery. Pump life is dependent on the flow rate of the pump. The pump is warranted for two years. The pump must be replaced prior to the battery dying.

I hereby state that I have read and understand this document and terms of agreement. I have had the opportunity to ask my doctor questions about the SynchroMed II Infusion System and these questions have been answered to my satisfaction. I believe that I have adequate knowledge of intrathecal medication therapy via the SynchroMed II system and its potential risks, complications, and benefits to give my informed consent to treatment.

Patient Signature: _____ **Date:** _____