

# FAQ FOR HEALTHCARE PROFESSIONALS

## SYNCHROMED™ II TDD THERAPIES (ITB, MALIGNANT PAIN, NON-MALIGNANT PAIN) AND COVID-19

This resource provides information on questions that Medtronic has received related to targeted drug delivery (TDD) therapies and the COVID-19 pandemic.

### For all TDD therapies, Medtronic recommends that HCPs:

- **Review and follow your facilities' emergency disaster procedures.**
- **Consider whether your patients have or should have current prescriptions for oral medications to supplement or replace their intrathecal treatment.\***
  - \* Note: Oral baclofen should not be relied upon as the sole treatment for intrathecal baclofen withdrawal syndrome.
    - More information can be found in the *Indications, drug stability, and emergency procedures Reference manual* for SynchroMed II™ and IsoMed®, which can be found here: <https://manuals.medtronic.com/manuals/main/region>
- **Ensure you have a complete list of patients with the dates of their upcoming refills. Confirm availability of the drug and the location for performing the refill in advance.**

Boxed Warnings for Lioresal® Intrathecal (baclofen injection), Infumorph® (morphine sulfate injection) and Prialt® (ziconotide) (for reference)

**Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.**

**Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).**

For more information, including **BOXED WARNING**, refer to Lioresal® Intrathecal (baclofen injection) prescribing information, located at [www.lioresal.com/prescribinginformation](http://www.lioresal.com/prescribinginformation), and the SynchroMed™ II brief statement, located at [www.medtronic.com/synch2](http://www.medtronic.com/synch2)

## **WARNING: RISKS WITH NEURAXIAL ADMINISTRATION; LIFE-THREATENING RESPIRATORY DEPRESSION; RISK OF ADDICTION, ABUSE, AND MISUSE; NEONATAL OPIOID WITHDRAWAL SYNDROME; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS**

### **Risks with Neuraxial Administration**

Because of the risk of severe adverse reactions when INFUMORPH is administered by the epidural or intrathecal route of administration, patients must be observed in a fully equipped and staffed environment for at least 24 hours after the initial (single) test dose and, as appropriate, for the first several days after catheter implantation [see [WARNINGS AND PRECAUTIONS \(5.1\)](#)].

### **Life-Threatening Respiratory Depression**

Serious, life-threatening, or fatal respiratory depression may occur with use of INFUMORPH. Monitor for respiratory depression, especially during initiation of INFUMORPH or following a dose increase. Patients must be observed in a fully equipped and staffed environment for at least 24 hours after each test dose and, as indicated, for the first several days after surgery [see [WARNINGS AND PRECAUTIONS \(5.2\)](#)].

### **Addiction, Abuse, and Misuse**

INFUMORPH exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing INFUMORPH, and monitor all patients regularly for the development of these behaviors and conditions [see [WARNINGS AND PRECAUTIONS \(5.3\)](#)].

### **Neonatal Opioid Withdrawal Syndrome**

Prolonged use of INFUMORPH during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available [see [WARNINGS AND PRECAUTIONS \(5.4\)](#)].

### **Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants**

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death [see [WARNINGS AND PRECAUTIONS \(5.5\)](#), [DRUG INTERACTIONS \(7\)](#)].

- Reserve concomitant prescribing of INFUMORPH and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

## **WARNING: NEUROPSYCHIATRIC ADVERSE REACTIONS**

**PRIALT is contraindicated in patients with a preexisting history of psychosis. Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Monitor all patients frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. Discontinue PRIALT therapy in the event of serious neurological or psychiatric signs or symptoms.**

## **Managing TDD patients**

1. What should I do if a patient needs a refill and cannot come to the hospital or a clinician cannot travel to them?

Medtronic's product labelling states:

*Patients must return to the clinic for refills at the prescribed times. Failure to return for refills at the prescribed times can result in the actual flow rate of the pump being less than expected, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose. Failure to return at the prescribed times can also damage the pump, requiring surgical replacement.*

However, the COVID-19 disease has caused many novel situations that can affect the availability of refill drugs and facilities in your area, the ability of the patient to travel, or access to where the patient is living. The healthcare provider and/or care team should maintain contact with their patients. Consider contacting your patients well in advance of planned refills to identify and mitigate any concerns.

There are options that you can consider:

- Option 1: Identify a home infusion service in your area that can refill and program pumps at the patient's current location.
  - Option 2: Consider if there are other facilities/clinics where the patient can obtain a refill in your area. Ensure these facilities have access to the drug solution to complete the refill. In light of COVID-19, the US Department of Health and Human Services has modified health care professional licensing regulations to allow HCPs to provide services in other states.<sup>1</sup> Many states have also modified their rules, so please check your local regulations to determine how these changes apply to you.
2. With our resources and personnel constrained due to COVID-19, I need to provide more training on managing pumps for physicians and mid-level healthcare professionals. Where can I find these resources?

Contact your Medtronic field representative or refer to the Medtronic TDD website (see Useful Resources at the end of this document). In case of any technical questions, contact our U.S. Patient and Technical Services Team: (800) 707-0933.

3. Do you have any additional guidance for patients?

In response to COVID-19, Medtronic has created a Patient FAQ webpage on Medtronic.com:

<https://www.medtronic.com/us-en/e/covid-19-faq-synchromed-ii-patients.html>

### **Extending Refill Intervals**

4. How do I extend time between my patients' refill visits?

Note: Changing drug concentration and adjusting other medications are medical management decisions to be based on the clinical judgement of the physician and discussion with the patient.

- If you are maintaining the same intrathecal daily dose (simple continuous or flex programming), increasing the drug concentration will extend the time until the next refill. There are important considerations that must be made before changing the drug concentrations.
  - Follow the instructions in the *Clinician Programmer Guide A810* ([link](#)) for changing the drug concentration (e.g. reservoir rinse, bridge bolus)
  - Drug stability varies. Refer to the appropriate drug labeling for complete prescribing information, including indications, contraindications, warnings, precautions, and adverse events. Refer to the *Indications, drug stability, and emergency procedures* Reference manual for information on drug stability in the SynchroMed II™ or IsoMed® pump. Links to drug labeling and Medtronic manuals can be found at the end of this document.
  - Higher concentrations require slower flow rates to maintain the same dose. Consider the potential impact on drug distribution in cerebrospinal fluid (CSF) with changes in flow rate. A change in flow rate may lead to increased or decreased clinical effects. Evidence shows that risk of inflammatory mass increases with higher opioid concentrations. If you are an HCP that has questions about drug distribution, you can contact RS Neuro Medical Affairs at [RS.NeuroMedicalAffairs@medtronic.com](mailto:RS.NeuroMedicalAffairs@medtronic.com).
  - Abrupt discontinuation of Lioresal® Intrathecal (baclofen injection) can lead to life-threatening withdrawal. Please refer to the Lioresal® Prescribing Information for information regarding the gradual reduction of Lioresal®.
- Consider lowering intrathecal dose and using oral medications to supplement.
- For patients receiving Infumorph® and also using myPTM™, consider the impact of limiting Patient-Activated Dosing on the refill interval.

If you have questions about programming or maximum refill interval, please contact US Patient and Technical Services Team: (800) 707-0933.

## **Treating patients who may have COVID-19**

### 5. How do I manage patients infected with COVID-19?

Follow COVID-19 guidelines which can be found on the World Health Organization ([WHO](#)) and Center for Disease Control ([CDC](#)) websites. There may be additional COVID-19 guidelines or requirements that may be in place from your local authorities.

### 6. How should I clean and disinfect the Model 8880T2 Communicator (telemetry head) and Model CT900 Clinician Tablet Programmer?

#### To clean and disinfect the communicator for COVID-19:

- Use commercially available disinfecting wipes that are labeled as having the ability to kill a virus, such as Sporidicin® Lysol® or Clorox®, or equivalent, and follow instructions on the container for cleaning hard nonporous surfaces.<sup>2</sup>
- Consider placing the communicator inside of a wipeable cover (e.g. non-sterile baggie or glove) per guidelines issued by the CDC.<sup>3</sup>

#### When cleaning the communicator and USB connector cable, use the following guidelines (per product manual):

- Keep liquid, including cleaning fluid, out of any openings
- Do not use spray cleaner directly on the communicator or USB connector cable
- Do not use harsh or caustic chemical products. Use water or a mild cleanser.
- Clean with a soft dry or lightly dampened cloth.

Full cleaning instructions can be found in Communicator Guide 8880T2 ([link](#)).

#### To clean the Clinician Programmer/Tablet (per tablet manufacturer, Samsung):

- *A lint-free, soft microfiber cleaning cloth is ideal for cleaning your tablet. You may also use a camera lens cleaning cloth. These are gentle and will not damage your tablet.*
- *Gently wipe the front and back of your programmer with the microfiber cloth. Do not apply too much pressure.*
- *You should avoid getting excess moisture onto your tablet; however, you may dampen the corner of the microfiber cloth with a small amount of distilled water.*

- *You can also use a disinfectant, such as a hypochlorous acid-based solution (containing 50-80ppm) or an alcohol-based solution (containing more than 70% ethanol or isopropyl alcohol). Do not apply these liquid solutions directly to your tablet; they should be carefully applied to a microfiber cloth instead.*
- *Avoid using cans of compressed air, as they may damage the surface of your phone.*
- *Do not use spray bleach on your tablet.*

Warning: To use the nonsterile programmer system components in a sterile field, place a sterile barrier between the patient and system components to prevent infection. Do not sterilize any components of the programmer system. Sterilization may damage the components.

Samsung Customer Service has informed Medtronic that Lysol® or Clorox® wipes would be appropriate for cleaning.

#### 7. What are other measures I can consider to limit exposure to COVID-19?

The CDC has published guidance to help assess the risk of exposure to COVID-19 for Health Care Professionals. One factor for determining risk is close contact with infected patients.<sup>4</sup>

- The CDC defines close contact for healthcare exposures as follows:
  - a) being within approximately 6 feet (2 meters), of a person with COVID-19 for a prolonged period of time (such as caring for or visiting the patient; or sitting within 6 feet of the patient in a healthcare waiting area or room); or
  - b) having unprotected direct contact with infectious secretions or excretions of the patient (e.g., being coughed on, touching used tissues with a bare hand).<sup>3</sup>
- To limit close contact with a patient, it is possible to program the pump while maintaining a distance of up to 3 meters [or 10 feet] between the communicator and clinician tablet. Make sure the communicator and clinician tablet are within range of each other (within 3 meters [10 feet]).

#### 8. How can Medtronic field representatives support me during this time?

Medtronic field representatives can provide education and technical support related to TDD therapies. Due to health care licensing laws, Medtronic sales representatives cannot change patient pump infusion settings even with a physician order.

Medtronic field employees, who work with customers in hospital settings, are collaborating with healthcare providers in new ways – like video chat for technical

support– to make every effort to reduce exposure to COVID-19. In situations where employees continue to work in clinical settings, we are following the WHO, CDC, and local hospital guidance to prioritize safety while helping doctors, nurses, and patient care teams.

## **Useful Resources for TDD**

### **Medtronic Links**

Medtronic Intrathecal Baclofen Therapy for Health Care Professionals Website:

<https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/neurological/intrathecal-baclofen-therapy.html>

Medtronic Targeted Drug Delivery for Health Care Professionals Website:

<https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/neurological/targeted-drug-delivery.html>

Medtronic Product Labelling

<http://manuals.medtronic.com/manuals/main/region>

### **TDD Drug Information Links**

Lioresal® Intrathecal (baclofen injection) websites (by Saol Therapeutics):

<https://saolrx.com/>

<http://lioresal.com/refill>

<http://Saolproductsupply.com>

Prescribing Information: [www.lioresal.com/wp-content/uploads/2019/03/Lioresal-PI-01-2019.pdf](http://www.lioresal.com/wp-content/uploads/2019/03/Lioresal-PI-01-2019.pdf)

Prialt® (ziconotide) intrathecal infusion website (by TerSera)

<https://www.prialt.com/>

Prescribing Information: [www.prialt.com/wp-content/uploads/prialt-prescribing-information.pdf](http://www.prialt.com/wp-content/uploads/prialt-prescribing-information.pdf)

Infumorph® (morphine sulfate injection) website (by Hikma):

<https://www.hikma.com/products/us-products/>

Prescribing Information: [www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=db9ac9e3-d761-4a99-9f34-4946ebe8f255](http://www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=db9ac9e3-d761-4a99-9f34-4946ebe8f255)

## **REFERENCES**

1. US Department of Health and Human Services. Waiver or Modification of Requirements Under Section 1135 of the Social Security Act. Public Health Emergency Website. <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid-19-13March20.aspx>; March 13, 2020. Accessed: April 7, 2020.
2. Medtronic data on file.
3. Center of Disease Control and Prevention. Cleaning and Disinfecting your facility. Coronavirus Disease 2019 (COVID-19) website. <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>. April 1, 2020. Accessed: April 7, 2020.
4. Center of Disease Control and Prevention. Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease (COVID-19) website. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>. March 7, 2020. Accessed: April 7, 2020.