



Medtronic, Inc.

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Technical Services: (800) 707-0933
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Dear Physician or Healthcare Provider,

We are writing to announce that Medtronic Neuromodulation has reached an agreement with the U.S. Food and Drug Administration (FDA) relating to the SynchroMed® drug infusion system and the Medtronic Neuromodulation quality system. This agreement, which is in the form of a consent decree, defines a path forward for Medtronic to complete certain corrections and enhancements to the SynchroMed pump and the Neuromodulation quality system. The decree requires Medtronic to comply with the FDA's Quality System regulation for medical devices, set forth in 21 CFR Part 820, and limits Medtronic's ability to manufacture and distribute the SynchroMed drug infusion system, unless specific conditions are met. To prevent disruption to patient care during this time, the FDA will allow limited manufacturing and distribution of SynchroMed drug infusion pumps for currently implanted patients who require a replacement, and with new patients under conditions of medical necessity, as described below.

Under this agreement, Medtronic is required to implement a plan to make certain changes to the SynchroMed drug infusion pump. These will include design changes to address issues previously communicated in medical device correction notices, which can be found at <http://professional.medtronic.com/pt/neuro/idd/ind/product-advisories>. The agreement also requires Medtronic to engage an independent expert to inspect the Neuromodulation quality system, processes, and records and to obtain the expert's certification that the system is in compliance with the requirements of the decree. Once the compliance of Medtronic Neuromodulation's quality system is certified to the FDA's satisfaction, the limitations on manufacture and distribution of SynchroMed pumps will be lifted.

With this announcement, there is no new information to share about the safety and performance of the SynchroMed drug infusion system. In addition, there is no new action required on the part of patients presently using the system.

Medtronic may provide SynchroMed drug infusion pumps as follows:

- **Replacement Patients:** The agreement permits Medtronic to provide a replacement SynchroMed pump because existing pump patients may be adversely affected by suddenly discontinuing their use of the pump.
- **New Patients:** The agreement permits Medtronic to provide a SynchroMed pump for a new patient when, in the professional judgment of a physician, the pump is medically necessary to treat one or more of the following medical conditions, and the benefits of such treatment outweigh the risks: (i) severe spasticity; (ii) chronic intractable pain; (iii) severe chronic pain; or (iv) primary or metastatic cancer.

In order to fulfill a patient's need based on one of the two scenarios listed above, there will be a certification process provided by Medtronic for the purpose of documenting that the patient meets one of these two criteria. We recognize the additional time required to complete this certification and will strive to facilitate an efficient process.



The consent decree also allows Medtronic to continue to manufacture and distribute components and accessories to support currently implanted SynchroMed drug infusion systems. Examples of components and accessories include catheters, refill kits, catheter access port kits, catheter revision kits, and accessory kits. We do not want patients who currently use the SynchroMed system to be adversely affected by any delay in shipping such components and accessories.

Medtronic takes this action very seriously and we apologize for any inconvenience that this may cause. We are dedicated to supporting you and your patients during this time. If you have any questions or feedback, please call Medtronic Technical Services at (800) 707-0933.

Sincerely,

A handwritten signature in black ink that reads "Tom Tefft". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Tom Tefft
Senior Vice President and President
Medtronic Neuromodulation

A handwritten signature in black ink that reads "Julie A. Foster". The signature is cursive and clearly legible.

Julie Foster
General Manager and Vice President
Pain Stimulation/Targeted Drug Delivery



CERTIFICATION OF MEDICAL NECESSITY SYNCHROMED® DRUG INFUSION PUMP

To be completed by the patient's physician

I have received and reviewed the notification from Medtronic Neuromodulation regarding the agreement (Decree) between Medtronic and the U.S. Food and Drug Administration (FDA) concerning the manufacture and distribution of the SynchroMed drug infusion system.

I have discussed this agreement with my patient. Based on my consideration of the patient's condition during my medical evaluation, I have determined, in my professional judgment, that the SynchroMed drug infusion pump is medically necessary to treat the patient's condition and that the benefits of such treatment outweigh the risks.

From the list below, please indicate the medical condition that requires treatment with the SynchroMed drug infusion pump.

The patient suffers from:

- Chronic intractable pain
- Severe chronic pain
- Severe spasticity
- Primary or metastatic cancer

Physician Signature

Date

Physician Name (printed)

Contact Number



REPLACEMENT PUMP CERTIFICATION SYNCHROMED® DRUG INFUSION PUMP

To be completed by the patient's physician

I have received and reviewed the notification from Medtronic Neuromodulation regarding the agreement (Decree) between Medtronic and the U.S. Food and Drug Administration (FDA) concerning the manufacture and distribution of the SynchroMed drug infusion system.

I have discussed this agreement with my patient. My patient currently has a SynchroMed drug infusion pump implanted.

I am requesting a replacement SynchroMed drug infusion pump for this patient.

Physician Signature

Date

Physician Name (printed)

Contact Number