Medtronic

August 21, 2020

Subject: SynchroMed™ II new septa pump FDA approved

Dear Health Care Provider,

I am pleased to share that the FDA has approved the change in our supplier's manufacturing process for the SynchroMed™ II refill port and Catheter Access Port (CAP) septa. Medtronic has now fully satisfied biocompatibility testing requirements for these septa components. I thank you for your understanding as we have navigated this challenge and apologize for the added difficulty that our supply shortage has caused you and your patients.

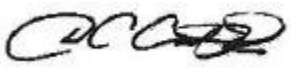
The biocompatibility test results confirm the safe use of SynchroMed™ II new septa pumps. In addition, FDA has communicated that its approval decision applies retrospectively to all previously implanted SynchroMed™ II new septa pumps. To help ensure the safety of patients currently implanted with a SynchroMed™ II pump, as well as those considering this critical therapy, Medtronic is urgently working to reach full commercial inventory of FDA-approved SynchroMed™ II new septa pumps. These are now available for both de novo and replacement implants for all indications to allow you to best manage the clinical needs of your patients.

Approval of the SynchroMed™ II new septa pump terminates the FDA Limited Enforcement Discretion requirements. You are no longer required to complete a Certificate of Replacement or include the potential risk information related to incomplete biocompatibility testing in your patient consents for pump replacement patients. If you have a patient that was implanted with the SynchroMed™ II new septa pump within the Limited Enforcement Discretion period of (June 1, 2020 – August 21, 2020), please inform the patient that our completed testing confirmed no risk for biocompatibility associated issues with use of the new septa and that their SynchroMed™ II pump is now FDA approved.

With termination of the FDA Limited Enforcement Discretion, Medtronic will resume full support of all de novo implants. The FDA will no longer require Compassionate Use requests for SynchroMed™ II chronic pain, cancer pain, and severe spasticity de novo implants.

In closing, the Medtronic team looks forward to once again providing the necessary product, service and support you and your patients expect and deserve. We remain fully committed to meeting the needs of all patients suffering from chronic pain, cancer pain and severe spasticity. If you have questions or require assistance, please contact your Medtronic field representative.

Sincerely,



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