carecentrix

Provider Newsflash Feb. 12, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued a Class 1 recall of all lots of Medtronic's MiniMed 630G insulin pumps distributed from September, 2016 to October, 2019 and all lots of MiniMed 670G insulin pumps distributed from June, 2017 to August, 2019 due to a missing or broken retainer ring which helps to lock the insulin cartridge into place in the pump's reservoir compartment. If not locked firmly into place, under or over delivery of insulin may occur resulting in hypoglycemia or hyperglycemia.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-minimed-insulin-pumps-incorrect-insulin-dosing?utm_campaign=Untitled%20Email&utm_medium=email&utm_source=Eloqu
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by:
    - Faxing information– To: 919-792-6718 Attn: Quality Department

Thank you for your prompt attention and cooperation in this matter.