Medtronic – Recall of Diabetes Infusion Sets

- On September 12, 2017, the FDA announced that Medtronic is conducting a voluntary recall of specific lots of infusion sets used with all models of Medtronic insulin pumps.

- Medtronic determined through recent field reports from patients and root cause analysis that the vent membrane in the recalled infusion sets may be susceptible to being blocked by fluid during the process of priming/fill-tubing. This situation can lead to potential over-delivery of insulin shortly after an infusion set change, which may cause hypoglycemia.

Medtronic Infusion Sets
Quick-set® Paradigm® Infusion Set
MiniMed® mio® Infusion Set
Silhouette® Paradigm® Infusion Set
Sure-T® Paradigm® Infusion Set
Quick-set® Luer Lock Infusion Set
Silhouette® Luer Lock Infusion Set
MiniMed™ Sure-T™ Infusion Set - Luer Lock

- Customers in the U.S. can determine if they have recalled infusion sets by visiting https://checklots.medtronicdiabetes.com.

- The recall is related to a certain discontinued component in these infusion sets and does not include insulin pumps or glucose sensors.

- Currently manufactured infusion sets, available to patients since April 2017, include a design update of this component which Medtronic believes reduces the risk of insulin over-delivery after an infusion set change.

- Medtronic will work with patients to ensure recalled infusion sets with the discontinued component are returned and replaced with new infusion sets containing the updated component at no cost. Return instructions can be found here.

- Medtronic recommends that customers use only infusion sets made with the new and enhanced component, the membrane, starting with their next set change. Medtronic would like to remind customers that it is very important to carefully follow the Key Steps document included with the recall notification letter regarding the priming/fill-tubing process - especially if a person only has recalled infusion sets.

- Contact Medtronic at **1-800-204-7616** for further questions regarding this recall.

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