

Medtronic Recalls Infusion Sets

An infusion set is a thin plastic tube used to deliver insulin from an insulin pump to a diabetes patient, and is typically replaced by the patient every three days. Affected infusion sets are reference numbers MMT-396, MMT-397, MMT-398 and MMT-399 with lot numbers starting with the number "8." Medtronic recently discovered that approximately two percent of "Lot 8" Quick-set infusion sets (which represents approximately 60,000 infusion sets out of an estimated 3 million infusion sets currently with customers) may not work properly. The affected infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little insulin and may lead to serious injury or death.

Patients should discontinue using "Lot 8" Quick-set infusion sets. The lot number (for example 8XXXXXX) is clearly marked on both the product box label, and on each individual infusion set package. Visit the Medtronic Diabetes website at www.medtronicdiabetes.com/lot8 to view the labels of "Lot 8" Quick-set infusion sets.

Customers are being asked to return any affected infusion sets to the company.
Medtronic is providing customers with replacement Quick-set infusion sets at no additional charge.

"Lot 8" Quick-set infusion sets were distributed in the United States, and in limited quantities in a small number of countries outside of the United States. The list of countries affected by this recall is available at www.medtronicdiabetes.com/lot8 or by contacting any Medtronic country office. No other Medtronic devices or infusion sets are involved in this recall.

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