



Medtronic

Medtronic, Inc.
18000 Devonshire Street
Northridge, CA 91325-1219

“LOT 8” QUICK-SET® INFUSION SET RECALL IMPORTANT THERAPY CONSIDERATIONS

Please review this information regarding therapy considerations associated with the “Lot 8” Quick-set infusion set recall:

“Lot 8” Quick-set® infusion sets are the only infusion sets affected by this recall. If you do not have replacement Quick-set infusion sets, **you can use any other Medtronic infusion sets you have been trained on and have available.** These include Quick-set infusion sets other than “Lot 8,” Silhouette® infusion sets, Sof-set QR® /Sof-set Ultimate QR® infusion sets, Sure-T® infusion sets and Polyfin® infusion sets for use with MiniMed Paradigm® insulin pumps. Any therapy adjustments, including the use of a different infusion set, should be made in consultation with your healthcare provider.

If circumstances occur where you do not have an alternative infusion set available, one option is to revert to the back-up injection plan established with your doctor. Please be aware of the following risks associated with continued use of “Lot 8” Quick-set infusion sets:

Risks Associated with Using “Lot 8” Quick-set Infusion Sets

Too Much Insulin Can be Delivered

- Changes in air pressure could cause too much insulin to be delivered when using an infusion set that does not vent properly.
- A rapid change in air pressure may cause a significant over delivery of insulin that may not be detected until after it has occurred.
- Examples where an increase in altitude can change air pressure include when an airplane is taking off, and when traveling from sea level to a higher elevation, such as driving up a mountain.

Any sign or symptom of hypoglycemia requires immediate attention and treatment.

Too Little Insulin Can be Delivered

- Even at stable altitude or stable air pressure, insulin delivery can be interrupted when using an infusion set that does not vent properly.
- The priming process builds up air pressure in the reservoir compartment and makes the insulin pump appear to be working properly when it is not.
- As always with insulin pump therapy, any interruption in insulin delivery would be detected through frequent blood glucose monitoring.

When blood glucose does not respond to a correction dose, you must always suspect that the infusion set is not working properly. Therefore, be prepared to give an injection and change your infusion set.