

QUESTIONS & ANSWERS REGARDING THE “LOT 8” QUICK-SET® INFUSION SET RECALL

Q1. Why is Medtronic recalling “Lot 8” Quick-set® infusion sets?

A. Medtronic recently identified that approximately 2% of “Lot 8” Quick-set infusion sets used with MiniMed Paradigm® insulin pumps may not work properly – some of these infusion sets do not allow the insulin pump to vent. This can potentially cause too much or too little insulin to be delivered.

Q2. Are the vents fixed in Quick-set infusion sets? Has Medtronic stopped shipping “Lot 8” Quick-set infusion sets?

A. Yes. The venting issue has been fixed and Medtronic is no longer shipping “Lot 8” Quick-set infusion sets.

Q3. Are replacement Quick-set infusion sets safe to use?

A. Yes! With the venting issue fixed, you can feel perfectly comfortable using your replacement infusion sets.

Q4. What solution is my supplier providing to its customers affected by this recall?

A. Your supplier is exchanging, at no additional charge, unused “Lot 8” Quick-set infusion sets.

Q5. Does this recall affect all Quick-set infusion sets?

A. No. Only Paradigm Quick-set infusion sets that have lot numbers starting with the number “8” with the following reference numbers are affected by this recall: MMT-396, MMT-397, MMT-398 and MMT-399. Rest assured, all Medtronic infusion sets other than “Lot 8” Paradigm Quick-set infusion sets are fine to use.

Q6. May I wait a few days to change my infusion set? I just started using a “Lot 8” Quick-set infusion set and have a full insulin reservoir. I would prefer to use my insulin so I don’t waste it.

A. *Medtronic recommends that you stop using your “Lot 8” Quick-set infusion set right away*, even if you need to discard some insulin. Please know that Medtronic is making this recommendation for your safety.

PROCESS QUESTIONS

Q7. Who do I contact to return my unused “Lot 8” Quick-set infusion sets?

A. Because you have purchased “Lot 8” Quick-set infusion sets from a supplier, Medtronic does not have your prescriptions or patient records on file. For this reason, we ask that you contact your supplier to return and exchange unused “Lot 8” Quick-set infusion sets.

Q8. How do I return my unused “Lot 8” Quick-set infusion sets?

A. Contact your supplier to return/replace unused “Lot 8” Quick-set infusion sets.

Q9. Can I just throw away my unused “Lot 8” Quick-set infusion sets?

A. No, please do not throw them away. Your supplier needs to confirm that you’ve received this notification and ask that you return your unused “Lot 8” Quick-set infusion sets to your supplier.

Q10. What if I don't have any unused "Lot 8" Quick-set infusion sets?

- A. Please take a moment to notify your supplier, if even if you don't have any "Lot 8" Quick-set infusion sets to return. Your supplier needs to confirm that you've received this notification because your safety is our top priority.

ADDITIONAL QUESTIONS

Q11. Why do Paradigm Quick-set infusion sets have vents?

- A. All Paradigm infusion sets have vents incorporated into the tubing connector. The vents allow air, but not fluid, to pass in and out of the reservoir compartment. Venting is necessary to equalize the pressure in the reservoir compartment of the insulin pump with the surrounding atmosphere.

Q12. What is clogging the vents in approximately 2% of "Lot 8" Quick-set infusion sets?

- A. A lubricant clogged the vents on approximately 2% of "Lot 8" Quick-set infusion sets. The lubricant has been eliminated from the manufacturing process, so you can rest assured this is no longer a problem. All Medtronic infusion sets other than "Lot 8" Quick-set infusion sets are fine to use.

Q13. In what circumstance could too much insulin be delivered using a "Lot 8" Quick-set infusion set?

- A. When an infusion set does not vent properly, a rapid increase in altitude could cause too much insulin to be delivered. Examples of this include when an airplane is taking off, and traveling from sea level to a higher elevation, such as when driving up a mountain. A significant over delivery of insulin may not be detected until after it has occurred. This could cause severe low blood glucose and would require immediate attention and treatment. Do not fly in an airplane or engage in any activity that involves a significant increase in altitude if using "Lot 8" Quick-set infusion sets.

Q14. In what circumstances would too little insulin be delivered using a "Lot 8" Quick-set infusion set?

- A. When an infusion set does not vent properly, even at stable altitude or stable air pressure, insulin delivery can be interrupted. This happens because the priming process may build up air pressure in the reservoir compartment. The insulin pump could appear to be working properly when it is not. This might result in too little insulin being delivered, which could cause high blood glucose to occur. As always with insulin pump therapy, any interruption in insulin delivery can be detected through frequent blood glucose monitoring.

Q15. Which Medtronic infusion sets can I use with my MiniMed Paradigm® insulin pump?

- A. Only "Lot 8" Paradigm Quick-sets are affected by this recall. This means that any other Medtronic infusion set may be used to manage your diabetes. This includes Quick-sets other than "Lot 8," Silhouette® infusion sets, Sof-set® infusion sets, Sure-T® infusion sets and Polyfin® infusion sets for use with MiniMed Paradigm insulin pumps. To learn more about our infusion set options, visit our website at www.medtronicdiabetes.com. Any change to a new type of infusion set should be done in consultation with your healthcare provider.

Q16. How will it affect Medicare billing?

- A. Due to limited product availability, initial product shipments will only allow for a single box (10 infusion sets) to be shipped. Adjustments will have to be made to the entire shipment (including other supplies, such as reservoirs) in order to be able to bill for a 30-day supply instead of the usual 90-day supply.