Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in
Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No.29/Misc/03/2021-DC (355)

Date: 11th Oct 2021

MEDICAL DEVICE ALERT

DEVICE

MiniMed™ 600 Series Insulin Pumps (MiniMed 620G Insulin Pump/Pump Kits & MiniMed 640G Insulin Pump/Pump kit)

BACKGROUND

The MiniMed™ 600 series insulin pump is designed with a pump retainer ring to lock the reservoir in the insulin pump. There have been reported incidents of a loose reservoir that can no longer be locked into the pump. The reservoir can become loose due to a broken or missing retainer ring that prevents a proper lock.

If the retainer ring is damaged, loose or missing, and the user inserts reservoir back while the infusion set is still connected to the body, it could result in rapid and potentially large infusion of insulin, which could cause hypoglycemia. Severe hypoglycemia can be life-threatening or may result in death. Under-delivery could occur if reservoir is not properly locked, creating space and preventing pump from pushing expected insulin into the body, or if the pump stops working due to water ingress, which could cause hyperglycemia

Reason for Recall

- Medtronic is recalling the specified insulin pumps to replace any pump that has a clear retainer ring with one that has the updated black retainer ring at no charge. A replacement insulin pump will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump.
- Medtronic previously identified, and informed customers about missing or broken clear retainer ring of the MiniMed™ 630G and 670G insulin pumps. The retainer ring helps to lock the insulin cartridge into place in the pump's reservoir compartment. If the cartridge is not locked firmly into place, under or over delivery of insulin may occur, which could result in low blood sugar (hypoglycemia (https://medlineplus.gov/hypoglycemia.html)) or high blood sugar (hyperglycemia

(https://medlineplus.gov/hyperglycemia.html)). Severe hyperglycemia and hypoglycemia can be life-threatening or may result in death.

- Example of hypoglycemia risk - If the retainer ring is broken or becomes detached from the insulin pump, and the user inserts the reservoir back into the pump while the infusion set is still connected to the body, it could result in a rapid and potentially large infusion of insulin.
- Example of hyperglycemia risk - The under delivery of insulin could occur if the reservoir is not properly locked in place by the retainer ring, creating a space between the insulin pump and the reservoir, and prevents the pump from pushing the expected insulin into the body, or if the pump stops working due to water entering the insulin pump. This may also contribute to diabetic ketoacidosis.
- Serious injuries and deaths have been reported with the use of MiniMed™ 600 series insulin pumps, however those adverse events may not have been directly related to the damaged clear retainer rings that are the basis for this recall

Who May Be Affected

- Any person with diabetes who uses an affected Medtronic MiniMed™ insulin pump
- Health care providers who treat people with diabetes using the affected MiniMed™ insulin pumps

Important Note: CDSCO have not received any complaints from the market on this issue.

FURTHER DETAILS & CONTACTS

M/s India Medtronic Pvt. Ltd, Gurugram, Haryana had issued a Field Safety Notice which is attached herewith this alert.

M/s India Medtronic Pvt. Ltd.
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Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

> **October 5, 2021 UPDATE:** Medtronic updated this recall with information that Medtronic will replace any MiniMed™ 600 series insulin pump that has a clear retainer ring with one that has the updated black retainer ring at no charge. A replacement insulin pump will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump. If you have questions about this recall, call Medtronic's 24-Hour Technical Support line: 1-877-585-0106.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- MiniMed™ 600 Series Insulin Pumps
- Lot codes: Refer to the Medical Device Recalls database entry for each product.
- Distribution Dates:
  - Model 630G - September 2016 to February 2020
  - Model 670G - May 2015 to December 2020
- Devices Recalled in the U.S.: 463,464
- Date Initiated by Firm: November 21, 2019

Device Use

People who have Type 1 diabetes may use the MiniMed™ insulin pump to deliver insulin for the management of their diabetes.

- The Model 630G insulin pump may be used by persons sixteen years of age and older.
- The Model 670G insulin pump may be used by persons seven years of age and older.

Reason for Recall

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Medtronic previously identified, and informed customers about missing or broken clear retainer ring of the MiniMed™ 630G and 670G insulin pumps. The retainer ring helps to lock the insulin cartridge into place in the pump's reservoir compartment. If the cartridge is not locked firmly into place, under or over delivery of insulin may occur, which could result in low blood sugar (hypoglycemia (https://medlineplus.gov/hypoglycemia.html)) or high blood sugar (hyperglycemia (https://medlineplus.gov/hyperglycemia.html)). Severe hyperglycemia and hypoglycemia can be life-threatening or may result in death.

- Example of hypoglycemia risk - If the retainer ring is broken or becomes detached from the insulin pump, and the user inserts the reservoir back into the pump while the infusion set is still connected to the body, it could result in a rapid and potentially large infusion of insulin.
- Example of hyperglycemia risk - The under delivery of insulin could occur if the reservoir is not properly locked in place by the retainer ring, creating a space between the insulin pump and the reservoir, and prevents the pump from pushing the expected insulin into the body, or if the pump stops working due to water entering the insulin pump. This may also contribute to diabetic ketoacidosis.

Serious injuries and deaths have been reported with the use of MiniMed™ 600 series insulin pumps, however those adverse events may not have been directly related to the damaged clear retainer rings that are the basis for this recall.

Who May Be Affected

- Any person with diabetes who uses an affected Medtronic MiniMed™ insulin pump
- Health care providers who treat people with diabetes using the affected MiniMed™ insulin pumps

What to Do

On October 5, 2021, Medtronic notified customers by email and phone that the recall has been expanded to replace all MiniMed™ 600 series insulin pumps that contain the clear retainer ring.

Medtronic provided the following updated recommendations to customers:

- Determine if you have a clear retainer ring.
  - Users can visit www.medtronicdiabetes.com/retainer-ring-serial-number-look-up (https://www.medtronicdiabetes.com/retainer-ring-serial-number-look-up/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and enter the serial number of the pump to check to confirm that the pump has a clear retainer ring.

- Examine the retainer ring of the pump.
- If the retainer ring is loose, damaged, or missing or the reservoir does **NOT** lock into the pump:
    - Stop use of the pump and contact Medtronic for a replacement pump. If you stop using the pump, you should follow your doctor's recommendations and perform manual insulin injections. **DO NOT insert the reservoir back into your pump while connected because you could mistakenly give yourself a rapid, and possibly large, insulin bolus.**
- If the reservoir locks in place correctly and the retainer ring is not loose, damaged, or broken:
    - Continue using the pump until you receive your replacement pump.
    - Follow instructions provided by Medtronic to replace and use the pump.
        - check your current and new pump and retainer ring for damage every time you replace the insulin reservoir, or any time it is dropped or bumped.

In November 2019, Medtronic first communicated about this recall with instructions for customers to examine pumps for potential retainer ring damage and to contact Medtronic if the retainer ring appeared to be loose, damaged or missing.

Contact Information

Customers who have questions or need additional information or support about this recall should call the 24-hour Medtronic Technical Support at 877-585-0166.

Additional Resources

- Medtronic Patient Letter (https://www.medtronicdiabetes.com/customer-support/product-and-service-updates/notice15-letter) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Medical Device Recall Database Entry Model 620G (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=178299)
- Medical Device Recall Database Entry Model 640G (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=178300)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event

Reporting Program either online, by regular mail or by FAX.