

Unomedical A/S – Recall of VariSoft Infusion Set

- On November 27, 2023, [Unomedical A/S announced](#) a voluntary consumer-level recall of certain VariSoft Infusion Sets because there is a risk the connector may detach from the infusion set which will disrupt insulin delivery. If this occurs, insulin may continue to flow through the tubing that is now disconnected from the patient and the insulin pump would not recognize an infusion set problem and would not alert users.
- These products were distributed from October 25, 2022 to September 15, 2023.

Product Description	Model Numbers	Lot Number
VariSoft Infusion Sets	<u>1002827</u> , <u>1002828</u> , <u>1002830</u>	5388367; 5388357; 5388371; 5388362; 5388368; 5388366; 5388372; 5388376

- VariSoft is an infusion set used with Tandem insulin pumps for the subcutaneous infusion of insulin in the treatment of diabetes.
- The defect reported was caused by damage to the connector piece during manufacturing, resulting in the connector becoming detached more easily from the insulin set than expected. Disconnections occurring during sleep, or when otherwise not detected, may lead to hyperglycemia unless it is noticed and reconnected promptly.
- The defect may impact all users of the VariSoft Infusion Sets, especially:
 - Children and elderly patients who may not notice if the connector is detached or may not be able to communicate the disconnection or hyperglycemia symptoms
 - Children or active sleepers may be at higher risk for disconnection during sleep, when it is less likely to be noticed
 - Pregnant women and their developing fetus.
- There is a chance of death or life-threatening harm to individual patients using devices from these lots, requiring professional medical intervention.
- To date, there has been 1 reported injury. There have been no reports of death.
- Anyone with the affected products on hand should stop distribution and return product. Consumers should contact their healthcare provider if they have experienced any problems that may be related to using this infusion set.
- Any patients with the recalled VariSoft Infusion Set on hand should contact Tandem Customer Technical Support at **1-877-801-6901** or by email at Techsupport@tandemdiabetes.com for return and replacement information. Tandem will also be able to answer any questions regarding the recall.