Urgent Field Safety Notice

Regarding

Varisoft infusion sets

Recall
HCP Letter

11 October 2023

Sender:
Unomedical a/s
Persoonsgegevens

Dear Healthcare Provider,

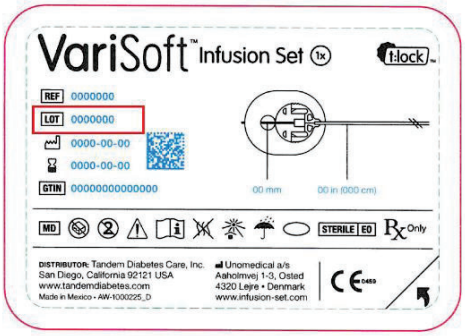
This Field Safety Notice is to inform you of a voluntary recall involving VariSoft infusion sets manufactured in 2022 with the following lot numbers: **5388367; 5388357; 5388371; 5388362; 5388368; 5388366; 5388372; 5388376.**

We would also like to make you aware that we will be notifying all patients who may be using Varisoft infusion set models. Patients will be emailed and/or sent a letter with information relevant to the Varisoft infusion set model number they use.

Description of problem:
Unomedical a/s has found that in rare cases the Varisoft infusion set connector detaches more easily from the infusion set than expected, requiring less force to disconnect than intended, thereby interrupting the delivery of insulin.

Actions to be taken:
If you have any of the affected infusion sets in your possession do not use them and, immediately contact your distributor for information regarding returning the affected infusion sets. You will be receiving replacement products. If all your Varisoft infusion sets stock is from the affected lots, please immediately contact your Healthcare Provider for guidance and instant replenishment. When using Varisoft infusion sets, it is important to handle the infusion set as per instruction in the Instruction For Use.

Details of affected devices:
Following lot numbers are in the scope of this recall:
5388367; 5388357; 5388371; 5388362; 5388368; 5388366; 5388372; 5388376
The Lot number is located next to the LOT symbol on the box and pouch labels



RISK to health:
Varisoft infusion set is intended for subcutaneous infusion of insulin administered by an external pump.
Hazard: Disconnected tubing from the infusion set.
Hazardous situation: Disconnection occurring during sleep where it is not detected, leading to missed basal dosing during sleep.
Harm: Elevated blood glucose and ketone level (nocturnal hyperglycemia). Diabetic ketoacidosis
Immediate consequences: Transient and marginally higher blood glucose level than intended.
Long range consequences: High blood glucose and ketone levels leading to diabetic ketoacidosis.
Long term consequences: Risk of ketoacidosis-related sequela such as microvascular and nerve damage.

Infants and children with increased nighttime movement activity may be more at risk but infusion would take place under the supervision of a parent, guardian, or caregiver. Patients who are critically ill or suffer from an infection are more at risk of rising blood sugar and ketone levels but it is presumed that they take extra precautions suitable for their individual situation.

Depth of the recall:
Unomedical a/s is as legal manufacturer obligated to reach out to all end users/consumers that have bought any of the affected lot. We therefore kindly ask for your full corporation.

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, or to report a complaint, please contact your distributor.

We appreciate your time and attention to this important notification.

Kind Regards

Persoonsgegevens

