



Urgent Medical Device Recall

TGA Recall Reference Number: RC-2023-RN-00909-1, ARTG No: 116234

[Product name: Regarding VariSoft Infusion Sets]

Customer Letter

19 October 2023

Sender:

AMSL Diabetes
2 McCabe Pl,
Chatswood NSW 2067
Australia

Dear Customer,

Australasian Medical & Scientific Ltd (AMSL), after consultation with the Therapeutic Goods Administration (TGA), is issuing a URGENT Medical Device Recall for VariSoft Infusion Sets. You are receiving this notification because our records indicate that we have supplied the affected devices to you.

This Field Safety Notice is to inform you of a recall involving VariSoft infusion sets with following lot and item numbers:

Lot Number	Item Number
5388357	1002827
5388368	1002830
5388372	1002827

You are receiving this letter because you might have received some of the affected infusion sets.

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, and thereby interrupting the delivery of insulin.

Actions to be taken:

Please examine your stock immediately to determine if you have any of the product lots referenced above on hand. If so, discontinue using with the lot(s) immediately. Please complete and return the enclosed form promptly via email to diabetes@amsl.com.au. Receiving responses from all customers will allow AMSL to evaluate the effectiveness of the recall process.

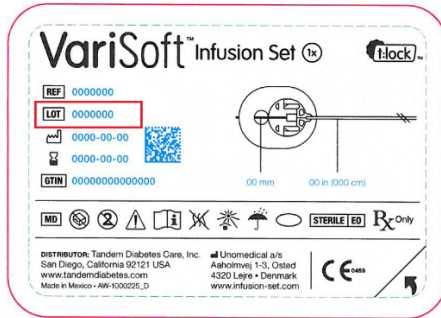
You will be receiving replacement products that do not have an increased risk of connector detachment and can therefore safely be used. When using VariSoft infusion sets, it is important to handle the infusion set as per instruction in the Instruction For Use.

Details of affected devices:

Globally the 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.

Infants and children are theoretically most at risk. The hazard results in infusion of 0.2 or 0.3 fewer units of insulin than intended, regardless of the infusion volume. Infants and children require a lower total amount of insulin than adults. Consequently, the hazard constitutes a higher fraction of their infusion volume compared with adults.

Infants and children with increased nighttime movement activity may be more at risk but are presumed to be closely monitored by a guardian (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.

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 AMSL by emailing diabetes@amsl.com.au or calling 1300 851 056.

We appreciate your time and attention to this important notification.

Kind Regards



Leane Beasley
AMSL Diabetes