

Urgent Field Safety Notice
Patient Letter

Regarding
Autosoft 90 infusion sets

21 July 2022

Sender:

Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

Dear Customer,

This letter is to inform you of a correction involving Autosoft 90 infusion sets listed in the attached sheet.

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

Description of problem:

Unomedical a/s has found that in the Instructions For Use (IFU) the value for Item 14 "Fill cannula with insulin" an *incorrect* value of 0.1 unit is stated for the 6 mm type and an *incorrect* value of 0.2 unit is stated for the 9mm type. The correct fill volume values are: 0.3 units for the 6 mm type and 0.5 units for the 9 mm type.

Actions to be taken:

The only action required is to use the correct value of 0.3 units for the 6 mm type and the correct value of 0.5 units for the 9 mm type when performing step 14 in the Instructions For Use.

FILLING THE CANNULA

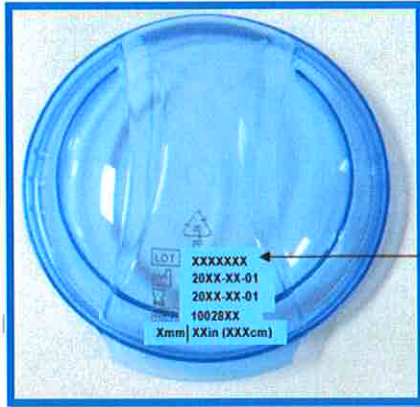
U-100 INSULIN:

6 mm: 0.3 units (0.003 ml)

9 mm: 0.5 units (0.005 ml)

Details of affected devices:

The product list attached to correction contains all lot numbers included in the scope of this.



Lot Number

Your LOT number is printed on the product as shown in the picture

RISK to health:

Autosoft 90 infusion set is intended for subcutaneous infusion of insulin administered by an external pump. Infusion of fewer units of insulin than expected can result in a higher blood glucose level than aimed for. A minimal volume of air being injected into the subcutaneous space does not have clinical significance. The patient, caregiver, or health care provider is expected to notice potential suboptimal blood glucose levels and administrate an additional dose as applicable. Subsequent infusions following the first infusion will perform as intended.

Immediate consequences: Transient and marginally higher blood glucose level than intended.

Long range consequences: None

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.

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 Tandem Helpline.

We appreciate your time and attention to this important notification.

Kind Regards

Lene Bastholm

Associate Director, Quality Compliance Engineering

Unomedical a/s