

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

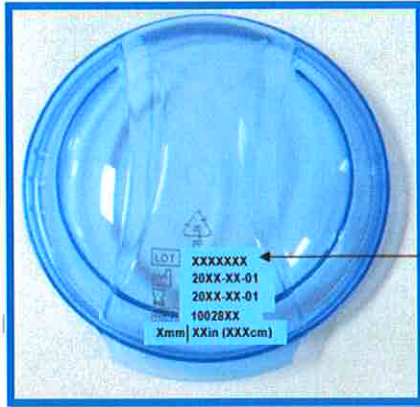
U-100 INSULIN:

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

Model No.	Lot
1002817	5372743
1002820	5372762
1002819	5372758
1002824	5376469
1002817	5381082
1002817	5381087
1002819	5381114
1002817	5381083
1002817	5381088
1002817	5381091
1002817	5381159
1002819	5372759
1002817	5381084
1002819	5381115
1002817	5381089
1002817	5381160
1002819	5372756
1002817	5381092
1002817	5381094
1002817	5381156
1002817	5381157
1002817	5381090
1002820	5381123
1002817	5381158
1002819	5381117
1002822	5381135
1002819	5381118
1002820	5381124
1002822	5381136
1002817	5372745
1002817	5381085
1002818	5381110
1002821	5381126
1002817	5381093
1002817	5381086
1002817	5381101
1002818	5381111
1002821	5381127
1002817	5372744
1002817	5381095
1002817	5381096
1002817	5381097
1002817	5381099
1002817	5381098
1002817	5381100
1002817	5381162

Model No.	Lot
1002817	5381107
1002821	5381128
1002823	5381139
1002817	5381103
1002823	5381137
1002823	5381138
1002820	5383835
1002817	5381102
1002817	5381104
1002817	5381108
1002821	5381129
1002823	5381140
1002817	5381164
1002817	5381105
1002817	5381109
1002823	5381141
1002817	5381161
1002817	5381163
1002819	5381121
1002821	5381130
1000281	5381150
1000281	5381151
1000281	5381152
1000281	5381153
1002819	5381116
1002817	5381166
1002819	5381120
1000282	5381154
1000282	5381155
1002817	5381106
1002818	5381112
1002819	5381122
1002820	5381125
1002818	5381113
1002817	5381165
1002819	5381205
1002823	5381142
1002819	5381208
1002817	5381169
1002823	5381144
1002817	5381168
1002817	5381172
1002823	5381145
1002817	5381167
1002817	5381170
1002823	5381146

Model No.	Lot
1002823	5381147
1002823	5381143
1002817	5381171
1002821	5381133
1002823	5381148
1002823	5381149
1002821	5381134
1002817	5381173
1002817	5381178
1002823	5381230
1002821	5381132
1002817	5381175
1002823	5381229
1000281	5381244
1002817	5381179
1002817	5381180
1002821	5381131
1002817	5381176
1002823	5381232
1002817	5381174
1002821	5381218
1002823	5381231
1002823	5381233
1002819	5381202
1002821	5381223
1002817	5381177
1002821	5381219
1002823	5381234
1002819	5381119
1002819	5381204
1002819	5381203
1002821	5381221
1002817	5381181
1002821	5381220
1002817	5381182
1002819	5381207
1002818	5381200
1002817	5381183
1002819	5381206
1002822	5381228
1002817	5381184
1002819	5381209
1002821	5381222
1002824	5381243
1002820	5381215
1002823	5381235

Model No.	Lot
1002817	5381186
1002817	5381189
1002817	5381197
1002821	5381224
1002817	5381190
1002823	5381238
1002817	5381192
1002817	5381194

Model No.	Lot

Model No.	Lot