[redacted]

Urgent Field Safety Notice

Regarding
Varisoft Infusion Set

Recall

11 October 2023

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

Commercial name of product:
Varisoft

Type of action: Recall notification

Attention: Distributors and end users/consumers

Dear customer,

This to inform you of a voluntary recall involving Varisoft infusion sets. You are receiving this letter because you act as a distributor of the affected infusion sets.

Details of affected devices:
Varisoft infusion sets with following lot numbers are affected of this recall:
5388367; 5388357; 5388371; 5388362; 5388368; 5388366; 5388372; 5388376

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.

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.
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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 correction:
Unomedical a/s is as legal manufacturer obligated to reach out to all end users/consumers that have bought any of the affected lots. We therefore expect your full corporation and will bi-weekly request updated data on your successful contacts with potentially affected end-users.

Actions to be taken by the distributor/user:
Please immediately examine your stock and promptly quarantine the product lots mentioned above. All eight listed lot numbers are in the scope of this recall.

Please complete and return the enclosed response form by email as soon as possible, but no later than 19-Oct-2023.

In addition to what may be in your stock, if you have further distributed the products subject to this recall, please identify your customers and notify them at once of this product recall. Please monitor and reconcile the recall of product from your customers. You may use the enclosed Distribution Partner Template for this purpose.

Upon receipt of the completed response form, we will ask you to return any unused, affected devices to Unomedical A/S. We will make a reimbursement for the unused, affected products upon receipt after quality inspection.

In addition to what may be in your stock, if you have further distributed the products subject to this correction, please identify your customers and notify them at once of this recall notification. Please monitor and reconcile your communications to your customers/end-users. Please use enclosed Patient Letters and HCP Letters for this purpose.

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please call any of the two contact persons:

Rabi Gharabli – Senior Director - Sales, Infusion Care, +45 2023 9495 - Rabi.Gharabli@convatec.com
Thibaut Mouly - Product Manager, Infusion Care, +45 3164 8322 - thibaut.mouly@convatec.com
Please note the local time in Denmark, UTC +01:00.

To report a complaint regarding this document, please write to fsca-id@convatec.com where the complaint will be registered and handled accordingly.

We appreciate your time and attention to this important notification.

[redacted]

Enclosures:
Patient Letter
HCP Letter
Distribution Partner Template

Response Form - Unomedical a/s Autosoft 90 infusion sets

Please Email this completed Response Form to:

To:	Unomedical a/s
Email:	FSCA-ID@convatec.com
RE:	Voluntary Medical Device Recall – Varisoft Infusion sets

Customer name:	
Contact Person:	
Contact person Phone/mobil number:	

☐ I have read and understand the recall instructions provided in the letter dated 11-Oct-2023

☐ I have checked my stock and will return the inventory consisting of _____ Boxes

Lot number	**Quantity originally shipped to customer**	**Quantity of products available for return to Unomedical a/s**

Affected Varisoft Infusion sets:

Lot No.	**Customer Model No**	**Country code as defined in ISO 3166-1 or full country name**	**Lot Size**

Customer Signature_____ Date:_____

Urgent Field Safety Notice

Regarding

Varisoft infusion sets

Recall
HCP Letter

11 October 2023

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

Dear Healthcare Provider,

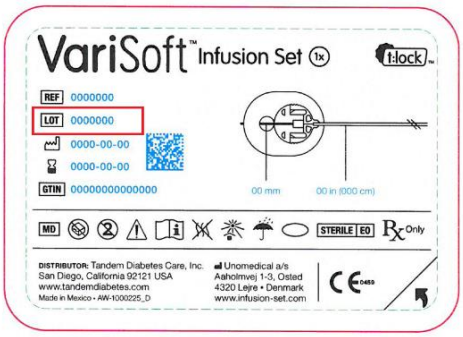
This Field Safety Notice is to inform you of a voluntary recall involving VariSoft infusion sets manufactured in 2022 with the following lot numbers: **5388367; 5388357; 5388371; 5388362; 5388368; 5388366; 5388372; 5388376.**

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.

[redacted]

Senior Director - Quality, Infusion Care, Unomedical a/s

Urgent Field Safety Notice

Regarding

Varisoft infusion sets

Recall
Patient Letter

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

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Actions to be taken:
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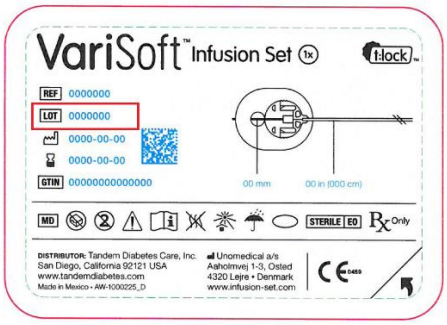

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Senior Director - Quality, Infusion Care, Unomedical a/s

