Urgent Field Safety Notice
Regarding
Steel cannula infusion sets

According to: MEDDEV 2.12/1 rev. 8 ANNEX 5

20/05/2015

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

Commercial name of product:
SURE-T, SURE-T Paradigm, contact detach, contact, Sub Q, neria, neria detach, neria multi, thalaset

Type of action: Field Safety Notification

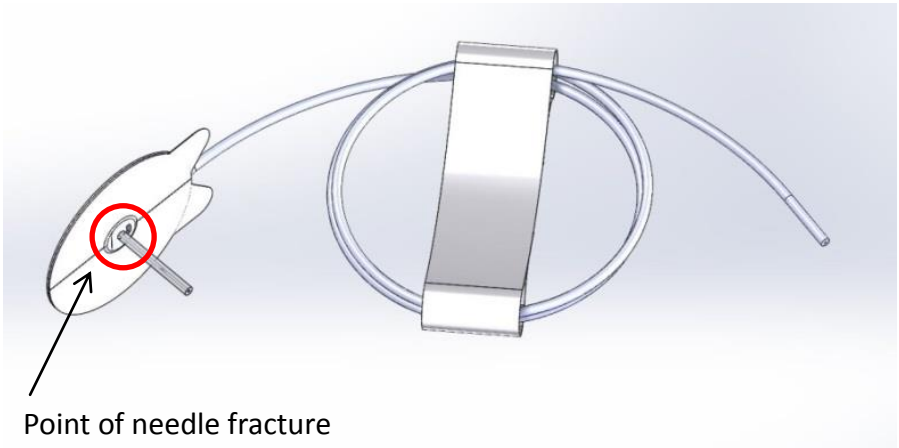
Attention: Distributors and end users/consumers

Dear Customer,

This is to inform you of a Field Safety Notice involving SURE-T, SURE-T Paradigm, contact detach, contact, Sub Q, neria, neria detach, neria multi, thalaset Steel cannula infusion sets listed in the attached sheet. These infusion sets are manufactured by Unomedical a/s and are used for subcutaneous infusion of insulin or medication.

You are receiving this letter because you act as a distributor of the above-mentioned infusion sets. We kindly ask you to present this information to those you supply.

Unomedical has, through its continuous quality management processes, found that in rare cases the steel needle can break during use. This can lead to leakage of medication, and the needle may require surgical removal. Unomedical has executed the required actions immediately to secure this issue.



By following the advice mentioned below and the instructions for use accompanying the devices, you can continue to use your infusion sets safely:

- Carefully remove the needle guard before inserting the infusion set.
- Do not bend the needle prior to insertion and do not use the infusion set if the needle is bent or has been damaged.
- Carefully remove the infusion set after use to avoid mechanical stress on the needle.
- Please ensure that the needle is present on the used infusion set before discarding it.
- Please contact your health care provider if you suspect that a needle has broken off and remained under the skin.

Details of affected devices:
The product list attached to this Field Safety Notice contains all of the lot numbers included in the scope of this notice.

Description of problem:
The listed infusion sets are manufactured by Unomedical a/s and are used for subcutaneous infusion of insulin or medication.

Unomedical has found that in rare cases the steel needle can break during its use, interrupting the delivery of insulin or medication.

Diabetes patients:
contact detach, Sure-T and Sure-T Paradigm is intended for subcutaneous infusion of insulin administered by an external pump. The interruption of insulin delivery can cause hyperglycemia which, if left untreated, can result in diabetic ketoacidosis (DKA). DKA is a serious condition that can cause a severe impact to health, including death. Symptoms of DKA may include nausea, vomiting, shortness of breath and excess thirst/urination. Seek medical attention immediately if you are experiencing any of these symptoms. In addition to the interruption of insulin delivery, the needle may require surgical removal.

Non Diabetes patients:
neria, Thalaset, neria Detach and neria Multi infusion sets are intended for subcutaneous infusion of immunoglobulins for treatment of Primary Immune Deficiency (PID), apomorphine for Parkinson's Disease (PD), morphine for pain management, and iron chelation therapy for Thalassaemia. The use of the infusion sets is indicated for up to 12-hour use.

Parkinson's Disease:
Apomorphine can be given as intermittent injections several times a day or as a continuous infusion using a small, portable pump during waking hours – normally for 12 hours. It is recommended to change the infusion set and site every 12 hours. As the patient is awake, it is likely the detachment would be noticed through leakage of fluid onto the clothing and skin and the potential return of symptoms.

PID:
When done subcutaneously, a high amount of IgG must be infused relatively fast (up to 60 ml) within one to two hours, which for some patients requires so-called furcated infusion sets, which most commonly is done once a week. The short duration of use means that any detachment is likely to be detected, and corrective action must be taken.

Pain management: Pain management is provided as a continuous subcutaneous infusion over four hours or longer by an external pump or a syringe driver. Routine clinical practice dictates that these patients have their infusion sets checked every four hours.

Thalassaemia: The use of an external infusion pump in the treatment of Thalassaemia is referred to as an iron chelation therapy. Iron chelation therapy aims at removing the overload of iron in a Thalassaemia patient as a result of the frequent blood transfusions necessary for a patient to survive.

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 and to show reconciliation data as proof. Therefore, we expect your full cooperation and will request the updated reconciliation data bi-weekly.

Actions to be taken by the distributor/user:

We kindly request that you, as the distributor, present this information to those you supply.

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

Torben Sandgren - VP Global Sales, Marketing and R&D: +45 6161 8354, Rabi Gharabli - Associate Director, Diabetes: +45 2023 9495, Kim Nielsen - Marketing & Portfolio Manager: +45 6155 5175

To report a complaint, please write to FSCA-ID@convatec.com, where the complaint will be registered and handled accordingly.

We appreciate you giving your time and attention to this important notification.

Best regards,

Mr Søren Melsted
Vice President QA/RA Infusion Devices & Industrial Sales

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

Response Form

Please email this completed response form to:

To: Unomedical a/s
Email: FSCA-ID@convatec.com
RE: Field Safety Notice - Steel cannula infusion sets

Please use capital letters:

Company name: _____
Contact person: _____
Position within company: _____
Contact person's phone/mobile number: _____

☐ I hereby confirm that the Field Safety Notice dated 20/05/2015 has been read and understood.
I also confirm that I will present this information to those I have supplied.

_____ _____
Signature Date