Urgent Medical device Recall

Regarding
Steel cannula infusion sets

According to MEDDEV 2.12/1 rev. 8 ANNEX 5

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20 may 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: Recall notification

Attention: Distributors and end users/consumers

Dear customer,

This Field Safety Notice is to inform you of a voluntary recall 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. You are receiving this letter because you act as a distributor of the affected infusion sets.

Details of affected devices:
The product list attached to this voluntary recall contains all lot numbers included in the scope of this.

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 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 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 Parkinsons 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.
Parkinsons: Apomorphine can be given as intermittent injections several times a day or as 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 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 1-2 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 taken.
Pain Management: Pain management is provided as a continuous subcutaneous infusion over 4 hours or longer by an external pump or a syringe driver. Routine clinical practice dictates that these patients have their infusion sits checked every 4 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 of 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. We therefore expect your full corporation and will bi-weekly request updated reconciliation data.

Actions to be taken by the distributor/user:

Please immediately examine your stock and promptly quarantine the product lots in the attached list. All listed lot numbers are in the scope of this recall.

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.

Please complete and return the enclosed response form by email as soon as possible, but no later than 06-09-2015

Upon receipt of the **completed** response form, we will issue a return material authorization (RMA) and ask you to return any unused, affected devices to Unomedical A/S. We will issue a credit for the unused, affected products upon receipt.

A copy of the letter to distributor and end users are attached to this letter

We sincerely apologize 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 your time and attention to this important notification.

Best Regards

[redacted]
Vice President QA/RA Infusion Devices & Industrial Sales

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

Response Form - Unomedical a/s Steel cannula infusion sets

Please Email this completed Response Form to:

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

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

☐ I have read and understand the recall instructions provided in the letter dated 05/20/2015

☐ 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 Steel cannula Infusion sets:

Lot number	Customer model number