carecentrix

Provider Newsflash
November 2023

FDA Recall – Unomedical A/S

Purpose of this communication:

- We are writing to inform you that the FDA has issued notice of a Class I recall of certain VariSoft Infusion Sets manufactured by Unomedical A/S from April 1, 2022 to August 1, 2022 and distributed October 25, 2022 to September 15, 2023 due to damage to the connector piece during manufacturing. Varisoft is an infusion set used with Tandem insulin pumps. The defect increases the risk of the connector becoming detached more easily from the insulin set than expected resulting in disruption of insulin delivery to the patient.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/unomedical-recalls-varisoft-infusion-sets-due-damage-connector-piece-causing-unexpected?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.