



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## **URGENT PRODUCT DEFECT CORRECTION\***

LEVEL: Consumer

CLASS: Class II

REFERENCE:RC-2019-RN-01587-1

DATE AGREED: 24/10/2019

**PRODUCT:** **Tandem t:slim X2 Insulin Pump - A/C Power Adapter**

ARTG 304681

(Australasian Medical & Scientific Ltd - Infusion pump, insulin, ambulatory)

**SPONSOR:** Australasian Medical & Scientific Ltd

**PHONE:** 1800 851 056 - AMSL Customer Service

**REASON:** AMSL advises that a potential safety issue has been identified with the A/C power adapters. This issue involves the A/C power adapters breaking apart, thus exposing the metal prongs contained within the adapters. This could cause injury if the exposed metal prongs were touched when the adapters were plugged into an electrical wall outlet.

There have been no reports of serious injury in relation to this issue to date.

**PROPOSED CUSTOMER ACTIONS:** Customers are advised to discard or destroy the three (3) power adapters that they initially received with the Tandem t:slim X2 insulin pump.

AMSL advises that along with the Customer Letter, affected customers will find a replacement adapter that has been manufactured under the new, corrected process.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 102 hospitals, healthcare professionals or organisations supplying to 4181 consumers nationally

Product export status: Unknown

This issue was first identified by the Sponsor

\*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>