



## Tandem TGA Suspension Notice FAQs – For Healthcare Professionals

27<sup>th</sup> November 2020

### **AMSL Diabetes/Tandem Diabetes Care Official Press Release**

Recently the Therapeutic Goods Administration (TGA) expressed concern about the Tandem Diabetes Care t:slim X2 insulin pump.

AMSL Diabetes and Tandem Diabetes Care have been in discussions with the TGA to address their concern. However the TGA have informed us of their intent to temporarily suspend the ARTG entry for the t:slim X2 insulin pump as of 24<sup>th</sup> November, 2020.

Existing t:slim X2 insulin pump users can continue to use their pump and order infusion sets and reservoirs/cartridges as usual. AMSL Diabetes will continue to replace t:slim X2 insulin pumps under the existing warranty policy.

AMSL Diabetes will not be able to supply new pumps to the Australian market until the suspension is lifted.

AMSL Diabetes and Tandem Diabetes Care are committed to the safety of their customers and to the quality of their products. We intend to work closely with the TGA to address the agency's concern and to resume continued market access for the t:slim X2 insulin pump as soon as possible.

For more information please contact our 24/7 Customer Care Team by emailing [diabetes@amsl.com.au](mailto:diabetes@amsl.com.au) or calling 1300 851 056.

### **FAQs**

#### **General Information**

##### **1. What are the TGA's specific safety concerns?**

There are a combination of hardware and software concerns. We are awaiting further guidance from the TGA before sharing additional information publicly.

##### **2. How long will this suspension be for?**

The suspension will be for 6 months as of 24<sup>th</sup> November and will end on 24<sup>th</sup> May 2021, unless lifted earlier.



### **3. Does this suspension affect any other countries?**

No, this product suspension has been identified by the TGA and therefore only affects Australia.

### **4. Do we need to recall pumps in the market?**

We have not been directed to recall pumps from the market.

### **5. Can we continue to supply replacement pumps and consumables?**

Yes, existing customers will continue to be supported by AMSL Diabetes and will still be able to access consumables. In-warranty customers will continue to be eligible for replacements under their existing warranty policy.

### **6. Is the t:slim X2 still suitable for use?**

The TGA have confirmed that existing customers can remain on their Tandem insulin pumps while AMSL Diabetes and Tandem work towards resolving their concerns.

### **7. Customer: I don't feel safe on the t:slim X2, what do I do?**

Please contact our Customer Care Team on [diabetes@amsl.com.au](mailto:diabetes@amsl.com.au) outlining your details and concerns and our team will review your situation.

### **8. When will I find out more information about this situation?**

As soon as we have more information, this will be made available on our website and our database. If you'd like to stay up to date with this notice, please sign up to our mailing list online here: [amsldiabetes.com.au/](http://amsldiabetes.com.au/)

## **Customer Enquiries – Ongoing Supply & Orders**

### **9. I just received my insulin pump prior to learning about this announcement, can I have a refund?**

If you have not started on the insulin pump, you may cancel your order and return the product. If you have started already on your insulin pump, there is no reason for you to discontinue your pump use. If you have any questions, please contact our Customer Care Team on [diabetes@amsl.com.au](mailto:diabetes@amsl.com.au).

### **10. I am due to start on my pump next week, will this still go ahead?**

- If your pump is already at the clinic with your HCP, then the pump start can go ahead.

- If the pump has yet to be dispatched from AMSL Diabetes, we cannot ship this until the suspension is lifted. We are happy to hold the pump order and reach out to you again once the suspension is lifted to confirm pump start details.

**11. I have submitted my paperwork, but the pump has not been shipped. What timeframe do you expect until pump starts can commence again?**

AMSL Diabetes and Tandem Diabetes Care are working closely with the TGA to ensure our continued compliance to global and Australian standards. At this stage we cannot provide any timelines for when sales of pumps will be able to commence in the Australian market again.

**12. My pump is at the clinic however I do not feel comfortable using it with the current suspension, can I return it?**

Yes you can return the insulin pump if it has not yet been opened and AMSL Diabetes will provide a refund to your Private Health Fund accordingly.

**13. What will happen with pending pump orders or loan pumps?**

As of 24<sup>th</sup> November 2020, AMSL Diabetes can no longer supply new pumps or any loan pumps from our warehouse until the suspension is lifted.

You will be contacted by AMSL Diabetes Customer Care regarding any pending pump orders, alternatively, please contact [diabetes@amsl.com.au](mailto:diabetes@amsl.com.au) or 1300 851 056.

**14. Can I still send through pump orders whilst waiting for the suspension to be lifted?**

Yes you can continue to submit pump orders however we are unable to process any orders until the suspension has been lifted.

**15. I am about to be out of warranty on my pump and am unable to order a new pump, how will I be supported by AMSL Diabetes?**

Your pump warranty will be extended until the suspension has been lifted; including the ability to update pump software.

AMSL Diabetes will continue to provide ongoing support to existing pump users.

All pump consumables are still able to be purchased as normal through your local NDSS Access Point/Pharmacy.



**16. I am out of warranty on my pump and am unable to order a new pump, how will I be supported by AMSL Diabetes?**

The warranty will be extended, until the suspension has been lifted; including the ability to update pump software.

AMSL Diabetes will continue to provide ongoing support to existing pump users.

All pump consumables are still able to be purchased as normal through your local NDSS Access Point/Pharmacy.

**17. Are software updates still available for existing customers?**

**In warranty customers:** Software updates can continue to all existing t:slim X2 insulin pump users.

**Out of warranty customers:** You are eligible to upgrade to the Basal-IQ technology until the suspension notice has been lifted.

**18. My loan pump will come to an end what should I do?**

All existing customers on a t:slim X2 loan pump can remain on their loan pump for the duration of the suspension. Loan pumps that are not being used must be returned to AMSL Diabetes.