



## URGENT: Field Safety Notice

2018-10-02

Gerald Simonds Healthcare Ltd.

9 March Place  
Gatehouse Way  
Aylesbury  
Buckinghamshire  
HP19 8UA  
United Kingdom

Dear Customer,

The purpose of this letter is to inform you that TiLite has voluntarily initiated a correction of certain Anti-Tip devices. The following models are affected by this correction:

TRA  
Aero T  
ZRA  
Aero Z  
2GX  
Aero X  
Twist  
Aero R

This correction decision has been made because of a potential failure of the extra short Anti-Tip device. If one or both Anti-Tip devices fail a user could fall back leading to a potential injury.

### **IMMEDIATE ACTIONS TO BE TAKEN BY THE DISTRIBUTOR/DEALER**

#### **LOG INTO CORRECTION WEB PORTAL**

Immediately access [www.tilitefsa.com](http://www.tilitefsa.com) and log in with the following ID and Password:

**ID:** USA(your TiLite account number)

**Password:** usa(your TiLite account number)2018

Please enter the ID and Password with no spaces; password must be lowercase. If you do not know your TiLite account number, please contact your area sales rep or customer service at 1-800-545-2266.

#### **CEASE DISTRIBUTION OF EXISTING INVENTORY**

Please examine your inventory for the serial numbers assigned to you, cease distribution, and quarantine the Anti-Tip devices from those chairs.



### **CONTACT END USERS**

Based on the serial number information provided in the Web Portal, immediately contact all end users of affected serial numbers to advise them of the requirement to correct their chair. A template end user letter is provided on the Web Portal that can be used to contact end users who require written communication for your records.

If you would like TiLite to communicate directly with the end user, please provide contact information including name, address, phone number and email address, if available.

### **PERFORMING THE CORRECTION**

If you will be performing the correction for your end users, a replacement kit will be provided for each serial number assigned to you. If you would like TiLite to perform the correction, we will provide the replacement kit after receiving the contact information from you.

The replacement kit will contain the following:

- Letter to end user describing the need for correction
- Replacement parts required to make the correction
- Detailed assembly instructions
- Return label to send original parts back to TiLite

If the original parts are no longer in the end user's possession, please contact TiLite for instructions on how to proceed.

Please contact Angel Maki at TiLite if you have any questions or concerns regarding this notice at 1-800-545-2266, extension 213, 8:00 AM to 5:00 PM Pacific Time, Monday – Friday or send an email to [US\\_Box\\_TiLite\\_Quality@permobil.com](mailto:US_Box_TiLite_Quality@permobil.com).

Sincerely,

A handwritten signature in black ink that reads 'WB Mick'.

WB Mick  
General Manager



## URGENT: Field Safety Notice

[MONTH DAY], 2018

[PERMOBIL CHAIR USER NAME]

[ADDRESS]

[CITY, STATE, ZIP]

Dear TiLite Chair User,

The purpose of this letter is to inform you that TiLite has voluntarily initiated a correction of certain TiLite Anti-Tip Devices. The following models are affected by this correction:

TRA  
Aero T  
ZRA  
Aero Z  
2GX  
Aero X  
Twist  
Aero R

This correction decision has been made because of a potential failure of the Anti-Tip device. If one or both Anti-Tip devices fail a user could fall back leading to a potential injury.

You are being notified because our records indicate you are in possession of one of these affected serial numbers. TiLite has identified the problem and is correcting these devices.

Your dealer will contact you to schedule an immediate inspection and replacement of the Anti-Tip devices and provide further instructions.

Please contact Angel Maki at TiLite if you have any questions or concerns regarding this notice or the safety and performance of your chair at 1-800-545-2266, extension 213, 8:00 AM to 5:00 PM Pacific Time, Monday – Friday or by email at [angelica.maki@permobil.com](mailto:angelica.maki@permobil.com).

Should you have any questions, please do not hesitate to contact us.

Sincerely,  
TiLite