



## **Urgent Field Safety Notice**

**Invacare TDX<sup>®</sup> SP Power Wheelchair with Stability Lock  
Distributed between August 2006 – September 2008; Serial Number Range 06HXXX –  
08IXXX**

**Invacare Ref: FSN 032**

Date: 5<sup>th</sup> August 2010

Ref: 2010/004/030/301/001

### **Urgent Safety Information:**

In the interests of the safety of our customers we would like to bring your attention to the TDX Field Action.

In November of 2007, Invacare initiated a recall for its TDXSP Power Wheelchair with Stability Lock. We are sending this second letter to expand on our original instructions and address issues that have been determined to exist with our stability lock feature and improvements implemented by Invacare.

- Please read this letter carefully because we need you to take additional actions that were not included in our initial letter.
- As a reminder, the issue being addressed for the safety of your customers is that the stability lock feature on some chairs may not be engaging properly or consistently.
- If the stability lock feature does not engage properly, the wheelchair may exhibit a tendency to do one or more of the following: (1) veer to one side; (2) rock forward onto its front riggings; (3) drive in an unintended circular motion; and/or (4) fall forward or to one side and injure the user.

As example situations that could occur if this feature is not corrected, a user's chair could fall off a ramp without guardrails and possibly have the chair fall on them, bump into nearby objects or be thrown from the chair. Consequently, and even though remote, an uncorrected Stability Lock feature could lead to **serious injury (i.e. broken bones, lacerations) or death** for the user due to loss of control of the wheelchair.

- The design of the stability lock, utilizing resistive cylinders, has generally proven quite effective, but in some cases the stability lock has failed to engage properly.
- These additional instructions are intended to address this failure.

**A list of your particular potentially affected units is provided on the enclosed sheet.**



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Please carefully read each of the four (4) sections below that contain detailed, step-by-step instructions for the actions that you need to take to help ensure the safety of your customers. If you do not understand or cannot perform what is being asked of you, please contact Invacare so arrangements can be made.

Invacare is requesting that you complete the required action **within 60 days of receipt of this letter.**

**STEP 1 of 4: IMMEDIATE COMMUNICATIONS NEEDED**

1. Please inform any customers to whom you have distributed this product about this recall.
2. Please immediately examine your inventory (including any demonstrator models) and quarantine (stop distribution or use) all units in your inventory that are subject to this recall.

**STEP 2 of 4: INSPECTION OF WHEELCHAIRS IN INVENTORY & IN FIELD**

Please inspect each wheelchair(s) on the enclosed tracking sheet to determine the **serial number** of the chair and which **version of the stability lock cylinder** is installed on the wheelchair.

Check for the **serial number**, by doing the following:

1. Face the rear of the wheelchair.
2. Look on the wheelchair's rear right swingarm for the serial number label.
3. Affected serial numbers for chairs with a **400 lb. weight capacity: 06Hxxxxx – 08Ixxxxx.**

Check for the **weight capacity** of the chair by doing the following:

1. Face the front of the wheelchair
2. Look either on the wheelchair's right front swingarm or underneath the joystick.
3. The weight capacity of the chair should be 400 lbs.

Check for the **version of stability lock cylinder** installed on the wheelchair by doing the following:

1. Look at the part number label on the cylinder (silver label).
2. Determine if the label has a long alpha-numeric string from the manufacturer present on the label (see Fig.1 below). The alpha-numeric string does not have to match the string below. It just needs to be determined if this string is present. If so, the cylinders do not have to be replaced.
3. If the cylinder label does not have this long alpha-numeric string (see Fig.2 below), the cylinders on the chair have to be replaced.
4. If you are unable to determine which version of cylinder is on the chair, please follow the instructions in Step 3 of 4 to have the cylinders replaced.



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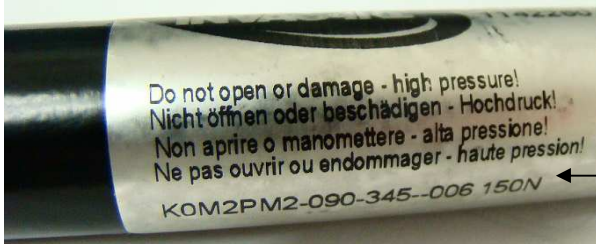


Fig. 1



Fig. 2

**NOTE: IF YOU HAVE DIFFICULTY IN DETERMINING THE SERIAL NUMBER OR WEIGHT CAPACITY OF THE WHEELCHAIR, PLEASE CONTACT INVACARE USING THE CONTACT INFORMATION AT THE END OF THIS LETTER.**

**STEP 3 of 4: CORRECTIVE ACTION REQUIRED TO CORRECT STABILITY LOCK FEATURE**

There are different actions Invacare is requesting you take of the chair, its serial number and the version of stability lock cylinder that is present on the chair. Please read the following instructions carefully. If you do not understand what is being asked, please contact Invacare.

**For Wheelchairs That Have A Serial Number That Falls Between 07JXXX to 08IXXX:**

1. If the serial number label looks like Fig.1, no further action is required.
2. If the serial number label looks like Fig.2, please order kit number 1164008.
3. To order kits, please contact your local Invacare Sales Company.

Instructions for installing the stability lock cylinders and/or the adjustment washers will be contained in the kits that you order.

**STEP 4 of 4: DOCUMENTATION FOR COMPLIANCE WITH THIS RECALL**

This recall is being monitored by the US Food and Drug Administration (FDA) and/or Health Canada.

For each unit that you correct, please document your actions on the enclosed tracking sheet and either **fax back or e-mail Invacare UK Technical Services Department. Invacare will credit your account £60 for each wheelchair with Stability Lock that you take the required corrective action.**

Invacare realizes that this inspection, adjustment and installation is an inconvenience, however it is necessary and must be done immediately to prevent the remote chance of **serious injury or death to your customers.**



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This recall is to be carried out to the end-user level. Invacare is requesting that you complete this action **within 60 days of receipt of this letter**. If you are unable or unwilling to perform this fix or to contact your end-users or those to whom the end user has given the device, please indicate this on the enclosed response form and provide Invacare with a list of the names and addresses of the customers to whom you distributed the device and we will contact them.

Please be advised that if you have purchased products from within the affected serial number ranges you will be notified separately by Invacare.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and / or any organisation where the potentially affected devices have been transferred. Please also ensure that awareness is maintained for an appropriate period.

Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

**Thank you very much for your cooperation. If you have any additional questions pertaining to this urgent recall, please contact your local Sales Company**

#### **Technical Services Department**

Tel. 01656 776 333

Fax. 01656 776 330

Invacare confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.



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List of Serial Numbers of the affected chairs:

08EE000260 060813491996  
08EE000261 060813491997  
08EE000259 060813492001  
08EE000258 060813492003  
08EE000928 060813733247  
08EE000929 060813756872  
08EE000933 060813781382  
08EE000938 060813792883  
08EE000939 060813804728  
08EE000931 060813811081  
08FE001664 060813834571  
08EE000936 060813840420  
08EE000934 060813840556  
08EE000932 060813846619  
08EE000937 060813846628  
08EE000930 060813846633  
08FE001660 060813846666  
08EE000935 060813852596  
08FE001672 060813876139  
08FE001662 060813905013  
08FE001651 060813975525  
08FE001653 060813993772  
08FE001650 060814005020  
08FE001656 060814017088  
08FE001649 060814017089  
08FE001665 060814029354  
08FE001652 060814029355  
08FE001669 060814046668  
08FE001670 060814088199  
08FE001658 060814100283  
08FE001655 060814164134  
08FE001657 060814187328  
08HE000591 060814187521  
08FE001671 060814205035  
08HE000588 060814234827  
08HE000592 060814234828  
08HE000593 060814252209  
08HE000581 060814270958  
08HE000582 060814276883  
08HE000597 060814276929  
08FE001673 060814288221  
08HE000578 060814288240  
08HE000584 060814294469  
08HE000585 060814294491



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08HE000595 060814300382  
08HE000576 060814306840  
08HE000590 060814312664  
08HE000586 060814330836  
08HE000579 060814336905  
08FE001668 060814343023  
08FE001663 060814343070  
08FE001666 060814349384  
08HE000577 060814360658  
08FE001661 060814366842  
08GE003334 060814384963  
08GE003343 060814432960  
08IE000841 060814439074  
08IE000861 060814439311  
08GE003352 060814462820  
08GE003346 060814506696  
08GE003344 060814518153  
08IE000854 060814530400  
08IE000839 060814530446  
08GE003335 060814542441  
08GE003338 060814548552  
08GE003337 060814554537  
08GE003332 060814590551  
08GE003348 060814596918  
08GE003353 060814597174  
08GE003342 060814620892  
08IE000846 060914681138  
08GE003347 060914687270  
08GE003355 060914699345  
08GE003354 060914716519  
08IE000843 060914752851  
08IE000856 060914765603  
08IE000847 060914771534  
08IE000840 060914771536  
08IE000838 060914788740  
08IE000851 060914789014  
08IE000849 060914794964  
08IE000855 060915245477  
08IE000850 060915250939



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## Customer Response to Field Safety Corrective Action – FSN 032

Action Completed – Please tick below	
Distribution of amended IFU	
Replacement kit / parts fitted	

This is to confirm that the necessary corrective action, as documented in the Field Safety Notice, FSN 032, dated 05/08/10, is now complete.

Please send fax-back form to the relevant Invacare office:

**Customers in UK: fax number 01656 776244**  
**Customers in Ireland: fax number 01 8107085**

The serial number(s) of the repaired product(s) are as follows:

### Action Completed

Signed.....

Company.....

Contact No.....

Date.....

**N.B.** Please include all the serial numbers listed above on your invoice, this will enable Invacare to process your invoice quickly and ensure payment.

**You have a responsibility under the Medical Device Directive to notify the manufacturer when corrective actions have been completed.**



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