

Medical Device Field Correction- January 2015

URGENT – MEDICAL DEVICE RECALL

Invacare® FDX®, TDX® series and Storm Series® power wheelchairs with 20”-24” width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back

Date Recall Launched: January 16, 2015

A field correction is being conducted for Invacare® FDX®, TDX® series and Storm Series® power wheelchairs with 20”-24” width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back manufactured between October 1, 2006 and July 31, 2014.

Invacare has recently identified a potential pinch point affecting the wiring involving Invacare® FDX®, TDX® series and Storm Series (3G) ® power wheelchairs with 20”-24” width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back. There is a possibility that if the slack in the wires is not routed and secured correctly, and with flexing of the back pan under the user’s weight, the headrest knob or clamp bracket may pinch, damage or cut the wire creating a hazard. Smoking, sparking, burning or fire may occur if any wire in this area is repetitively pinched at the same location over a period of time. Not all impacted chairs are expected to have slack in the wiring that is not routed and secured correctly.

To date, Invacare has received one complaint and there have not been any reported events involving injury associated with this issue. However, Invacare takes patient safety seriously, and the Company wants to ensure this potential wire routing issue is not present with the potentially impacted wheelchairs with power recline seating systems and conventional style back.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA) and Health Canada and is subject to effectiveness checks.

Units manufactured between: October 1, 2006 and July 31, 2014.

Impacted Serial Numbers: See Attachment 1

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