



Yes, you can:

URGENT – MEDICAL DEVICE FIELD ACTION
Invacare® Hydraulic Patient Lifts
(Model Numbers 9805 and 9805P)

Date: November 16, 2018

Dear Consumer:

This letter is to provide you with important information concerning a field corrective action involving hydraulic patient lifts (see impacted models listed below).

What is the problem?

Invacare has identified via customer complaints, the potential for the mounting bolt connecting the caster to the base frame of the patient lifts to become loose. Loose hardware can cause wear to the hardware and housings. If left unresolved, the caster may separate from the base of the lift causing the Lift to tilt and a patient fall. Failure does not occur right away but happens over time if the lift is not properly maintained.

What is the risk?

Patient falls are inherently dangerous and may result in a range of injuries that are dependent on physical condition of the patient and the nature of the fall. When injuries occur, they are typically non-serious injuries such as bruising, lacerations, or abrasions. In rare cases, more serious injuries such as bone fracture, head trauma, or death can occur.

For caregivers using the lift, attempts to manually stabilize a lift if it becomes unstable could result in sprains, serious back injuries, or bone fractures.

Why are you being contacted?

According to our records, you received one or more potentially impacted hydraulic patient lifts.

What units are affected?

Finished Device: Invacare® Hydraulic Patient Lifts, models 9805 and 9805P, with serial numbers ranging between 09FSZ590001 and 16ESZ104075 are potentially affected. Impacted units will have serial numbers beginning with the following:

| | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|
| | 10ASZ | 11ASZ | 12ASZ | 13ASZ | 14ASZ | 15ASZ | 16ASZ |
| | 10BSZ | 11BSZ | 12BSZ | 13BSZ | 14BSZ | 15BSZ | 16BSZ |
| | 10CSZ | 11CSZ | 12CSZ | 13CSZ | 14CSZ | 15CSZ | 16CSZ |
| | 10DSZ | 11DSZ | 12DSZ | 13DSZ | 14DSZ | 15DSZ | 16DSZ |
| | 10ESZ | 11ESZ | 12ESZ | 13ESZ | 14ESZ | 15ESZ | 16ESZ |
| 09FSZ | 10FSZ | 11FSZ | 12FSZ | 13FSZ | 14FSZ | 15FSZ | |
| 09GSZ | 10GSZ | 11GSZ | 12GSZ | 13GSZ | 14GSZ | 15GSZ | |
| 09HSZ | 10HSZ | 11HSZ | 12HSZ | 13HSZ | 14HSZ | 15HSZ | |
| 09ISZ | 10ISZ | 11ISZ | 12ISZ | 13ISZ | 14ISZ | 15ISZ | |
| 09JSZ | 10JSZ | 11JSZ | 12JSZ | 13JSZ | 14JSZ | 15JSZ | |
| 09KSZ | 10KSZ | 11KSZ | 12KSZ | 13KSZ | 14KSZ | 15KSZ | |
| 09LSZ | 10LSZ | 11LSZ | 12LSZ | 13LSZ | 14LSZ | 15LSZ | |

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Form: 79

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What actions are required?

1. Continue to have your patient lift(s) inspected and maintained by a qualified service provider at the intervals defined within your User Manual.
2. Continue to check for loose fasteners or hardware prior to each use.
3. Should you find loose fasteners or hardware, contact a qualified service provider to perform maintenance. Do not attempt to perform maintenance yourself.

This voluntary field action, which will be classified by the U.S. Food and Drug Administration (FDA), is being conducted with the knowledge of the FDA and Health Canada and is subject to FDA effectiveness checks.

If you have any questions concerning these instructions, please call Invacare's recall and field action support line at (877) 413-6008, Monday – Friday, 8 a.m. – 5 p.m. EST, for assistance. Visit www.invacare.com/recall for more information about this field action.

Thank you for your immediate attention to this important matter. We appreciate your cooperation.

Sincerely,

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| <p style="text-align: center;"><i>Provider:</i></p> <p style="text-align: center;"><i>Affix Your Business Card Here</i></p> |
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