



## **Urgent Field Safety Notice**

### **Action 3NG / Adjustable backcane failure**

Date: 25<sup>th</sup> October 2010

**Invacare Ref: FSN 034**

Ref: VR 2010 002 019 401 009 (#4923)

#### **Urgent Safety Information:**

In the interests of the safety of our customers we would like to bring your attention to a potential welding failure of angle adjustable backcane on Action 3NG wheelchair. The problem affects a batch of 58 chairs produced from 1<sup>st</sup> November 2009 to 2<sup>nd</sup> April 2010.



Invacare recommend that wherever feasible, you refrain from using your chair until the suspect parts have been replaced. The failure of backcane could result in a fall from the wheelchair and injury to the user.

Replacement parts will be sent to you, free of charge.

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® Limited  
Pencoed Technology Park ·  
Pencoed · Bridgend CF35 5HZ  
Tel: +44 1 656 776 222  
Fax: +44 1 656 776 220

Invacare® Ireland Ltd  
Unit 5 · Seatown Business Campus  
Seatown Road · SWORDS · County,  
Dublin  
Tel. +353 1 8107084  
Fax +353 1 8107085



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;

**Technical Services Department**

Tel. 01656 776333

Fax. 01656 776330

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

Serial number of affected wheelchairs				
050919126501	050919296869	050919477417	051019829119	051020062620
050919134252	050919317194	050919477765	051019885426	051020087952
050919140038	050919317330	050919604010	051019927096	051020107527
050919171578	050919324628	050919640180	051019940006	051020107540
050919186085	050919333600	050919661420	051019955052	051020140714
050919186568	050919334329	051019707763	051019978928	051020178166
050919195089	050919342563	051019715266	051019979060	051020217356
050919202196	050919383982	051019722185	051019987085	051020225329
050919228025	050919423053	051019754949	051019993748	051020263399
050919235166	050919463698	051019769329	051020033953	051020332567
050919273217	050919470020	051019777679	051020034002	
050919296551	050919477147	051019805069	051020047895	



Invacare® Limited  
Pencoed Technology Park ·  
Pencoed · Bridgend CF35 5HZ  
Tel: +44 1 656 776 222  
Fax: +44 1 656 776 220

Invacare® Ireland Ltd  
Unit 5 · Seatown Business Campus  
Seatown Road · SWORDS · County,  
Dublin  
Tel. +353 1 8107084  
Fax +353 1 8107085



## Customer Response to Field Safety Corrective Action – FSN 034

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 034, dated 25/10/10, 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.**



Invacare® Limited  
Pencoed Technology Park ·  
Pencoed · Bridgend CF35 5HZ  
Tel: +44 1 656 776 222  
Fax: +44 1 656 776 220

Invacare® Ireland Ltd  
Unit 5 · Seatown Business Campus  
Seatown Road · SWORDS · County, Dublin  
Tel. +353 1 8107084  
Fax +353 1 8107085