

Urgent FIELD SAFETY NOTICE

Invacare Dolomite Futura – Device exchange

Date: 2016-09-12

Invacare ref: 513546

MPA ref 6.6.3-2014-46357

Important Safety Information

In the interest of the safety of our customers we would like to bring a non-conformity of a certain affected batches of Futura rollators to your attention.

Description of the problem

Our Post market surveillance shows an increase of reports with broken front forks of Invacare Dolomite Futura, manufactured during September 1, 2012 up to and including April 30, 2014.

The cases where injury occurred have been reviewed by Invacare medical experts, and external medical experts, who see a low probability that such an injury would result in serious injuries needing more than temporary medical or surgical intervention.

Advice on action to be taken by the customer

- Please be advised that if you have purchased rollators from within the affected serial number range you will be notified separately by Invacare.
- Affected rollators: All models of Invacare Dolomite Futura, manufactured September 1, 2012 to April 30, 2014.
- For affected rollators, the complete rollator needs to be exchanged, and the exchanged rollator needs to be scrapped.
- Affected rollators can be identified by serial numbers on the serial label attached to the device.



Manufacturing month of this rollator is January 2014 (2014-01), serial number is G024-153068

- Invacare will provide you with a list of which individual affected rollators that has been distributed to you, including serial numbers for these rollators.
- Exchange rollators can be ordered on Article number in the attached table from Invacare free of charge.
- Invacare recommend that the rollators are exchanged during the normal maintenance of the product. Note that yearly maintenance is recommended according to the User manual of the rollator.
- Invacare need confirmation of completed action.
 - o Serial number of exchanged (old) rollators.
 - o Confirmation that exchanged (old) rollators are scrapped.
- The action will start in **September 12,** 2016 in the following European countries, IS, NO, NL, FR, CH and DE.

Attached

- Template for customer response to Field Safety Corrective Action
- Table with Article numbers to order replacement rollators free of charge.

Please ensure that the information in this field safety notice is made available to all relevant personnel within your organization and / or customer base, and that awareness is maintained for an appropriate period.

Relevant National Competent Authorities will be advised of the FSCA.

If you have any questions relating to this field service notification, or should you require any additional information, please contact:

Invacare Technical Services Department

Tel. :

E-mail :

Web :

Fax. :

Response to Field Safety Corrective Action – FSN 513546

This is to confirm that the necessary corrective action, as documented in the Field Safety Notice, FSN 513546, dated 2016-09-12, is now completed for the below stated rollators.

Action Completed – Please fill in the boxes below	
State name of attached excel-file with serial numbers for all exchanged (old) rollators: Alternatively, serial numbers for exchanged (old) rollators:	
Total number of exchanged (old) rollators:	
Affirmation that all exchanged (old) rollators have been scrapped:	

The monthly follow-up shall include serial numbers of exchanged (old) rollators until the last day in the previous month. Example: Follow-up done in November 2016, includes all rollators repaired from the start of the action in September 2016, until October 31, 2016.

Please send a scanned copy of this signed sheet and, if applicable, the corresponding excel-file of completed rollators, to Invacare Sales representative at **namename@invacare.com**, latest the 15th of each month until this field action is completed.

Action Completed

Signed.....Date.....

Company.....

Contact phone and mail.....

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

Article numbers for ordering replacement Rollators free of charge

Please find the Article number the original rollator was ordered on.

Select the corresponding Article number starting with letters FA and order on that number.

Accessories from the replaced rollator needs to be transferred to the replacement rollator.

I2070-43-21	FAI2070-43-21
I2070-43-23	FAI2070-43-21
I2070-43-27	FAI2070-43-21
I2072-13-9006	FAI2072-13-9006
I2072-13-9008	FAI2072-13-9008
I2072-13-9009	FAI2072-13-9006
I2072-43-21	FAI2072-43-21
I2072-43-23	FAI2072-43-21
I2072-43-27	FAI2072-43-21
I2072-43-9006	FAI2072-43-21
I2074-13-9006	FAI2074-13-9006
I2074-13-9009	FAI2074-13-9006
I2074-43-21	FAI2074-43-21
I2074-43-27	FAI2074-43-21
I2074-43-9006	FAI2074-43-21
I2076-43-21	FAI2076-43-21
I2076-43-23	FAI2076-43-21
I2076-43-27	FAI2076-43-21
I2081-43-01	FAI2081-43-01
I2082-43-01	FAI2082-43-01
I2082-43-24	FAI2082-43-24

Also note that at the end of this Field Safety Corrective Action the number of ordered rollators will be reconciled with your submitted serial numbers of scrapped rollators.

Please note that the replacement rollator will have the original Article number, not the FA letters on serial label or on the marking on the package box.