



Urgent Field Safety Notice

Birdie & Flamingo Lifters

Date: 01st June 2012

Invacare Ref: FSN 044

IMB ref: V14764

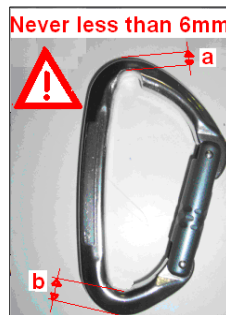
MHRA ref: 2012/005/009/291/017

Urgent Safety Information:

In the interests of the safety of our customers we would like to advise owners and users, that we have been made aware of several incidents involving the carabiner fitted to Birdie and Flamingo lifters.

1. Wear on Carabiner

The carabiner used to attach the spreader bar to the lifter, may show some wear in cases of intensive / severe use. The carabiner should be checked regularly, and replaced if the thickness of its sections (dimension “a” and “b”) measures less than 6 mm (as illustrated below). This information was included in the User Manual, starting **SN 091105631721** (March/2011).



To prevent wear, we have changed the material of the carabiner from aluminium to steel. All Birdie Lifters after **SN 091106013501** (from November 2011), have already been upgraded with the new steel carabiner.

Durability tests show that the steel carabiner should not wear significantly even when tested to 9 times more cyclic tests than required by the standard, which is 10,000 cycles. A **Steel carabiner meets Invacare's more stringent requirements.**



Invacare® Limited
Pencoed Technology Park ·
Pencoed · Bridgend CF35 5AQ
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



2. Detachment of Carabiner from the Spreader bar

It has also been reported by some customers that under certain conditions the spreader bar may unintentionally unhook from the carabiner.

From history of first incidents reported, we had considered the swivel of Spreader bar could be related to the disengagement of Carabiner.

Tests were made to find the Rotation's "Safe Area" (specification) for Spreader bar, and it is under control since **SN 091105599253** (February 2011).

After some other incidents where the swivels of Spreader bar were correct, conclusion by Invacare was that it is not a technical failure and the root cause is not known.

Further preventive action was planned to reduce the probability of spreader bar disengagement. We will **Replace / Refit Steel Carabiner, assembled upside down**.

Due to a small change of carabiner's shape, it was also necessary to modify the plastic moulded part where the carabiner is fixed.

Due the fact that some Birdie lifters have already been improved with the Steel carabiner, we will need to proceed in two different ways:

a) All Birdie in the field **BEFORE** SN 091106013501

- Change the carabiner for the steel one (1449515) and assemble it, upside down
- Change plastic part (1509328)
- Change Labels (1511759 or 1511760 or 1514578 or 1522220 or 1528280), according Birdie model and correspondent Work Instruction (see attached List)
- Place a new label on the Mast (1180355)

b) All Birdie in the field **AFTER** SN 091106013501

- Remove the Carabiner in Steel and Refit assembling it upside down
- Change Labels (1511759 or 1511760 or 1514578 or 1522220 or 1528280), according Birdie model and correspondent Work Instruction (see attached List)
- Place a new label on the Mast (1180355)



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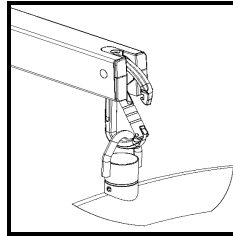
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Unit 5 · Seatown Business Campus
Seatown Road · SWORDS · County,
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Tel. +353 1 8107084
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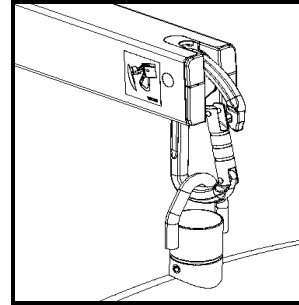
**Carabiner in Steel
(1449515)**



**Plastic part
(1509328)**



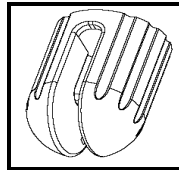
**New Label
(1180355)**



**New Assembly of
Steel Carabiner**

c) All Flamingo Lifters in the field

- Change plastic part (1422019) for a new one (1180247)



- Change the carabiner for the Steel one (1449515) and assemble it, upside down

A Work Instruction for the correct way to do the replacement is attached to this Field Safety Notice.

Also an Addendum to the User Manual will be send with this information.

Also a Replacement Kit with all above mentioned parts, is available for you to order (see attached List with corresponding Item number).

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.



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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.



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Customer Response to Field Safety Corrective Action – FSN 044

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 044, dated 01st June 2012, 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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