
Urgent Field Safety Notice

High-low:x frames manufactured by R82 A/S

FSCA-identifier 24th October 2008

Corrective Action: Retrofitting of safety plate on size 2 High-low:x frames from R82 A/S

Date: 24th October 2008

Attention: Danish Medicines Agency
CA (in markets where the size 2 High-low:x frames have been distributed)
National dealers
End users/institutions/suppliers (via the national dealers)

Details on affected devices:

Size 2 High-low:x frames manufactured by R82 A/S the period 24.08.2007 – 03.10.2008 with the following article numbers:

8911605-02, 8911605-02E, 8911606-02, 8911615-02, 8911615-02E, 8911616-02

Description of the problem:

We have experienced breakage in the welding on the adaptor for the High-low:x which may cause the adaptor to tilt forwards. There is potential that the user could suffer serious injury should they rotate forwards with the seat and impact the floor. In order to avoid unintended forward tilt an additional safety plate is now mounted on new frames in our production and should also be retrofitted on frames already in use.

This is to further enhance the safe use of the size 2 High-low:x.

The safety plates along with the necessary tools will be sent out together with mounting instructions for correct fitting in paper format as well as a CD with video footage of the retrofitting. The relevant number of kits of safety plates will be sent to our national dealers that are to ensure this retrofitting – either themselves or by forwarding the parts and information to end users, institutions and suppliers.

If you have any further questions please get more comprehensive information from R82 or by contacting your national dealer.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (if appropriate).

Please transfer this notice to other organisations on which this action has an impact (if appropriate).

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).

Contact reference person:

[REDACTED]

Quality Manager

R82 A/S

Parallelsvej 3

D-8751 Gedved

e-mail: [REDACTED]

Phone: +45 79685 [REDACTED]

R82 A/S

[REDACTED]

Quality Manager