

Follow-up Field Safety Notice – Jenx Ly-on

FSN-016B

19th September 2024

For the attention of:

All users, carers, prescribers, healthcare organisations, and distributors.



1. Products affected

Product Code	Description	UDI-DI	Size	Compatible with
LY01-03	Ly-on Green	5056235200253	One size	NA

2. Description of the identified issue

Our post-market surveillance (PMS) process and review of our user risk assessment has identified a high risk of the device being used incorrectly, by allowing weight to be applied to the side rail when placed in the lateral position. This can cause undue stress to be placed on the locking mechanism and potentially result in the locking mechanism failing.

3. Actions taken by the manufacturer

- As a corrective action, the supplier will manufacture, test, and approve a new bracket (estimated 4 months).
- The supplier will supply and fit new support brackets to the side rails (estimated 6 months from availability of the replacement part), provide updated instructions for use and warning labels, conduct an audit, and provide additional training on the correct use of the side rail.

4. Actions to be taken by the user/user's representative

The supplier advises all responsible persons, healthcare professionals, and all other users to stop using the device until further notice.

Please contact us immediately with the information below, using the contact details given in section 6 so we can arrange field safety corrective actions:

- Full address of the location of the product
- Serial number of the product (this is the code that begins with 'JX...')
- Phone number of the person who can grant access to the product
- Email address of the person who can grant access to the product

- If you no longer have a Ly-on, please let us know

5. Action to be taken by organisations and distributors

Continued awareness and vigilance is important to ensure the corrective action identified in this FSN is effective, and that the product is no longer used.

- Distribute this FSN to any person within your organisation and/or to any customer where the affected parts may have been allocated or sold
- Continue to monitor responses to ensure that all affected products in your supply chain have been identified
- Contact us with details of the location of the product

6. Contact Details

Territory	Contact name	Contact email	Contact telephone
UK and ROI	Jiraffe	hello@jiraffe.org.uk	0114 285 3376
Rest of World	Export	export@jenx.com	0114 285 3376 (or account manager)

Manufacturer Contact Person

To confirm this notice has been forwarded to the appropriate regulatory agencies for and on behalf of Jenx Ltd,


Signed:



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