



Initial Field Safety Notice – Ly-on

FSN-016A

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 new brackets (time-line TBC).
- The supplier will supply and fit new support brackets to the side rails, provide updated instructions for use and warning labels, conduct an audit, and provide additional training on the correct use of the side rail (timeline TBC).
- Further information will be provided in the follow-up field safety notice, FSN-016B.

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

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

5. Contact Details

National Contact Point Information	
National contact point organisation name Jenx Ltd	Name of the contact person Luke Parry
E-mail luke.parry@jenx.com	Phone +44 (0)7538 941743
Country GB	Address Wardsend Road
City name Sheffield	Postcode S6 1RQ

Manufacturer Contact Reference Person

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

Signed:



Luke Parry

Head of Research & Development