



## Initial Field Safety Notice – Ly-on

FSN-016A

19<sup>th</sup> 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 (timeline 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	
<b>National contact point organisation name</b> Jenx Ltd	<b>Name of the contact person</b> Luke Parry
<b>E-mail</b> luke.parry@jenx.com	<b>Phone</b> +44 (0)7538 941743
<b>Country</b> GB	<b>Address</b> Wardsend Road
<b>City name</b> Sheffield	<b>Postcode</b> 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