



Urgent Field Safety Notice – PU Support Pads

FSN-014A

23rd September 2020

For the attention of: All users, carers, prescribers and distributors.

Products affected

The affected products were manufactured between November 2019 and September 2020.

Product Code	Description	Size	Compatible with
DM36	Dreama slim support pad	One size	Dreama

Images of affected items are given in appendix i.

Description of the identified issue:

A small number of products (DM36) have been identified as an issue: As part of the design of DM36 the inserts that attach the small PU pad to the bracket are manufactured from plywood sheet material. In this instance the identified affected products may have been manufactured from a plywood sheet material containing structural defects. This reduces the strength of the fitting which can result in the plywood delaminating and the support pad breaking off the bracket when placed under pressure over time.

Actions taken by manufacturer

- The manufacturing process is currently under review and a redesign of the component is taking place.
- The manufacturing process has been reviewed and the plywood insert redesigned in Steel.
- Replacement of all affected products.

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

- There is a risk of injury if the affected items break in use. Breakage may occur without warning and the affected items cannot be easily identified upon inspection, therefore **the item identified above should be taken out of use immediately. ONLY the identified part is required to be removed, any other Dreama system components remain safe for use.**
- Await further contact from your distributor to instruct when replacement part will be fitted.

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.

- 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 parts in your supply chain have been identified.

Contact Details

If you have any queries or require clarification please use the contact details below.

Territory	Contact name	Contact email	Contact telephone
UK & Ireland	Jiraffe	hello@jiraffe.org.uk	0114 285 3376

Manufacturer Contact Reference Person

Daniel Limb - Director
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To confirm this notice has been forwarded to the appropriate Regulatory Agencies for and on behalf of Jenx Ltd.

Signed:

