



Urgent Field Safety Notice – PU Support Pads

FSN-013A

4th June 2020

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

Products affected

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

Product Code	Description	Size	Compatible with
DM36	Dreama slim support pad	One size	Dreama
JB26	Short slim support pads	2	Junior, Junior +, Multiseat
MB14	Short slim support pads	2	Multiseat
MB31	Therapy bench pelvic support pack	One size	Therapy Bench

images of affected items are given in appendix i.

Description of the identified issue:

A small number of products have been identified in which the inserts that attach the small PU pad to the bracket may have been inserted the wrong way around. This reduces the strength of the fitting which can result in the support pad breaking off the bracket when placed under pressure.

As per the Instructions for Use all pads should be assessed for any damage prior to each use – if pad show signs of cracking or are found to be loose on the brackets then they must not be used.

Actions taken by manufacturer

- The manufacturing process is currently under review.
- Increased quality monitoring has been put in place to ensure the integrity of products until a permanent preventative solution is found.
- 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 **all items identified above should be taken out of use immediately.**

1. Please complete the attached FSN reply form and return via email to the contact listed below. On receipt of the reply form a replacement part will be sent to you.
2. Upon receipt of your replacement part please return the affected part using the return instructions provided and complete and return the confirmation of corrective action complete form which will be provided with your replacement parts.

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.

1. Distribute this FSN to any person within your organisation and/or to any customer where the affected parts may have been allocated or sold.
2. Instruct those who you are distributing this FSN to, to complete the reply form attached and return these to you.
3. Continue to monitor responses to ensure that all affected parts in your supply chain have been identified and replaced.

Contact Details

Please return the attached FSN reply form to the email address given below. If you have any queries or require clarification please use the contact details below.


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

Manufacturer Contact Reference Person

Daniel Limb - Director
 Jenx Ltd, Herries Road, Sheffield,
 +44 (0)114 285 3376
daniel.limb@jenx.com

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

Signed:





Field Safety Notice Reply Form – FSN-013A

IMPORTANT: RESPONSE REQUIRED

Please complete and return this form to the email address given in the FSN

Our records show that you have received one or more affected support pads manufactured between November 2019 and May 2020. Please complete and return this form urgently.

Contact Name	
Organisation Name (if applicable)	
Address	
Job Title	
Phone No.	
Email address	
Date	
Signature	

1. Do you still have the affected products?

Yes		Please return this form
No – transferred elsewhere		Please complete part 2 and return this form
No – disposed of		Please return this form

2. If you have transferred the affected products elsewhere please give details of the new location and contact details below and return this form.

Name	
Address	
Telephone	
Email	

FSN-013A Appendix i.

Products affected

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

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DM36	Dreama slim support pad	One size	Dreama



JB26	Short slim support pads	2	Junior, Junior +, Multiseat
MB14	Short slim support pads	2	Multiseat



Please note the height of the metal bracket is 20mm for JB26 and 30mm for MB14

MB31	Therapy bench pelvic support pack	One size	Therapy Bench
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