

MySling HighBack Clip Slings – Possible risk due to incorrect sizing

Ref: FSN1001, 25/08/22.

Dear Customer,

Our records indicate that you may currently be using our MySling range of HighBack patient specific slings with Clip attachments.

We recently made some modifications to the sling's design intended to improve patient comfort, however it has become apparent that these modifications have also increased the sling's sizing requirements. This means, for example, that a patient previously sized as large may now be medium.

Whilst the sling remains safe to use if correctly sized, we understand that some patients may have been assessed using the original design sling. In this case it is important that they are properly reassessed by a suitably qualified individual before being issued with a new sling. Alternatively, we will replace any unused product you have with new units in the original design, free of charge, or we will provide a full refund.

All new and current orders will be fulfilled with the original design sling. We hope to make the modified design available through NHS Supply Chain at a future date if approved.

Please contact us using the contact details below if you have any questions.

We regret any inconvenience that this may cause, however we greatly appreciate your understanding and assistance as we take actions to ensure product quality and safety of our patients.

Yours sincerely,



Stephen Hall
Managing Director

1. Affected products

Product Codes

Product Code	UOM	Description
2510005	Box (10)	MySling High-Back (clip), S
2510006	Box (10)	MySling High-Back (clip), M
2510007	Box (10)	MySling High-Back (clip), L
2510008	Box (5)	MySling High-Back (clip), XL
2510009	Box (5)	MySling High-Back (clip), XXL

Shipment dates

Affected MySling Clip slings were shipped on or after 1 June 2022

Batch numbers

From	To
3408178	3410509
3410992	3414251
3474052	3492698
3519185	3523691

Batch numbers are printed on the exterior of the box. See Appendix I for batch number by product code.

2. Description of the problem

Sling design modifications have led to an increase in the sizing of all slings meaning that some patients may now require a smaller sling size in the new design compared to when they were assessed using the original sling design.

3. Potential risk

There is potential for a patient to fall through an incorrectly fitted sling resulting in serious injury. We have received a report where an individual has started to slip through the commode aperture opening when lifted.

This incident did not result in a fall, however, to avoid a more serious incident occurring we are advising that you take immediate corrective action.

4. Corrective action

Option 1

All patients are reassessed by a suitably qualified individual before being lifted using one of the affected products. Please refer to the updated sizing guide below when reassessing patients with the affected product.

Option 2

Remove all affected products from use and contact Lisclare to arrange collection using the contact details below. Any unused product will be replaced with new units in the original design, free of charge or refunded in full.

5. Additional information

When following option 1, please refer to the following sizing guide instead of the guide included with the original instructions:

Size	Width at Hips
XS	Under 36cm
S	36cm –41cm
M	41cm –48cm
L	41cm –48cm
XL	Over 56cm

Note: These patient measurements should be used as a rough guide to facilitate the initial selection of a sling and should be followed up with a full assessment of the sling's suitability by an appropriately qualified individual.

6. Action by customer

- i. Please ensure this Field Safety Notice is passed throughout your organisation to all departments who may be affected.
- ii. Implement the corrective action outlined above (either option 1 or 2).
- iii. Contact Lisclare Customer Services to arrange the uplift and replacement, or refund of any unused units you wish to return if applicable (corrective action option 2).
- iv. Complete and sign the Customer Response Form at Appendix II and return it to Lisclare at the address indicated.

7. Key contacts

Address for return of the Customer Response Form:

Lisclare
Unit 11 Heron Business Park
Tan House Lane
Widnes
WA8 0SW

Telephone 0151 495 5750, email quality@lisclare.com

Your local representatives:

South England & South Wales - Peter Bradburn, 07816 839 842, peter.bradburn@lisclare.com

North East England - Andrew Ponton, 07715 217 696, andrew.ponton@lisclare.com

North West England, N Wales - Matthew Wilson-Yelverton, 07714 797 678, matthew@lisclare.com

Scotland - Arron Hurn, 077 8875 7373, arron.hurn@lisclare.com

APPENDIX I - Batch number by product code

Item No.	Description	UOM	From	To
2510005	MySling High-Back (clip), S	Box (10)	3410992	3411542
2510005	MySling High-Back (clip), S	Box (10)	3521538	3521838
2510006	MySling High-Back (clip), M	Box (10)	3411543	3412743
2510006	MySling High-Back (clip), M	Box (10)	3474629	3475279
2510006	MySling High-Back (clip), M	Box (10)	3491576	3492136
2510006	MySling High-Back (clip), M	Box (10)	3521839	3523139
2510007	MySling High-Back (clip), L	Box (10)	3412744	3414094
2510007	MySling High-Back (clip), L	Box (10)	3475280	3475830
2510007	MySling High-Back (clip), L	Box (10)	3492137	3492557
2510007	MySling High-Back (clip), L	Box (10)	3523140	3523290
2510008	MySling High-Back (clip), XL	Box (5)	3414095	3414245
2510008	MySling High-Back (clip), XL	Box (5)	3523291	3523691
2510009	MySling High-Back (clip), XXL	Box (5)	3414246	3414251

Batch numbers are printed on the exterior of the box.

APPENDIX I – Customer Response Form (Response required)

Reference: MySling HighBack Clip Slings – Possible risk due to incorrect sizing

An acknowledgement is needed to satisfy the requirements outlined by the Medicines and Healthcare Products Regulatory Agency (MHRA) in compliance to this Field Safety Notice.

Please confirm that you have carried out one of the following options by ticking the appropriate box:

- I confirm that we do not have any of the products indicated by the affected batch numbers in Appendix I in use or in storage at our facility (**no action required**).
- I confirm that we have ensured that all patients will be reassessed before being lifted using one of these affected products (corrective action **Option 1**).
- I confirm that all products indicated by the affected batch numbers in Appendix I are removed from service and arrangements have been made with Lisclare for their return (corrective action **Option 2**). Please list the number of boxes you wish to return in the box below:

Code	UOM	Size	Qty	Refund or replace?
2510005	Box (10)	MySling High-Back (clip), S		
2510006	Box (10)	MySling High-Back (clip), M		
2510007	Box (10)	MySling High-Back (clip), L		
2510008	Box (5)	MySling High-Back (clip), XL		
2510009	Box (5)	MySling High-Back (clip), XXL		

Customer details & confirmation

Facility Name:					
Address:					
Contact Name:		Title:			
Contact number:		Email:			
Signed:				Date:	

Please post or scan and email a signed copy to: Lisclare, Unit 11 Heron Business Park, Tan House Lane. Widnes, WA8 0SW. Email address quality@lisclare.com.