

MySling HighBack Loop Slings – Possible risk due to incorrect sizing

Ref: FSN1002, 25/08/22.

Dear Customer,

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

We recently made some modifications to the sling’s design intended to improve patient comfort, however we are concerned that the modifications may have affected the sling’s sizing.

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 unless otherwise requested. 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
2500005	Box (10)	MySling High-Back (loop), S
2500006	Box (10)	MySling High-Back (loop), M
2500007	Box (10)	MySling High-Back (loop), L
2500008	Box (5)	MySling High-Back (loop), XL
2500013	Box (9)	MySling High-Back (loop), Mixed

Shipment dates

Affected MySling Loop slings were shipped on or after 1 July 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 may have affected the sling's sizing meaning that some patients may now require a different size sling 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 not received any reports of this kind to date, however, to reduce the risk of such an 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.

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. 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.

6. 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
2500005	MySling High-Back (loop), S	Box (10)	3408178	3408278
2500005	MySling High-Back (loop), S	Box (10)	3492558	3492698
2500005	MySling High-Back (loop), S	Box (10)	3519185	3519435
2500006	MySling High-Back (loop), M	Box (10)	3408279	3408679
2500006	MySling High-Back (loop), M	Box (10)	3474328	3474628
2500006	MySling High-Back (loop), M	Box (10)	3519436	3520236
2500007	MySling High-Back (loop), L	Box (10)	3408680	3409530
2500007	MySling High-Back (loop), L	Box (10)	3520237	3521537
2500008	MySling High-Back (loop), XL	Box (5)	3409531	3409606
2500008	MySling High-Back (loop), XL	Box (5)	3474052	3474327
2500013	MySling High-Back (loop), Mixed	Box (9)	3409607	3410509

Batch numbers are printed on the exterior of the box.

APPENDIX I – Customer Response Form (Response required)

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

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.