

Patient Handling Devices

GBUK Banana

Woodland House, Blackwood Hall Business Park
North Duffield, Selby, North Yorkshire YO8 5DD

T +44 (0) 1757 288 587
W www.gbukbanana.com
E info@gbukbanana.com

 @GBUK_Group
 @GBUKBanana
 GBUK Group
 GBUK Group



Urgent Field Safety Notice

FSCA Reference: 2023/012/019/601/050
Type of Action: Immediate Attention Required
Date: 19th December 2023

Product Description: Clip Sling, Slings Small
Product Code: B-SSPUC-S
Primary Packaging UDI: 5060405746168
NHSSC Code: FER14257
LOT Number: 230215

Product Description: Clip Sling, Slings Medium
Product Code: B-SSPUC-M
Primary Packaging UDI: 5060405746151
NHSSC Code: FER14254
LOT Number: 230215

Product Description: Clip Sling, Slings Large
Product Code: B-SSPUC-L
Primary Packaging UDI: 5060405746144
NHSSC Code: FER14258
LOT Number: 230215

Product Description: Clip Sling, Slings Extra Small
Product Code: B-SSPUC-XS
Primary Packaging UDI: 5060405746922
NHSSC Code: FER14259
LOT Number: 230615

Product Description: Clip Sling, Slings Small
Product Code: B-SSPUC-S
Primary Packaging UDI: 5060405746168
NHSSC Code: FER14257
LOT Number: 230615

Product Description: Clip Sling, Slings Medium
Product Code: B-SSPUC-M
Primary Packaging UDI: 5060405746151
NHSSC Code: FER14254
LOT Number: 230615

Product Description: Clip Sling, Slings Large
Product Code: B-SSPUC-L
Primary Packaging UDI: 5060405746144
NHSSC Code: FER14258
LOT Number: 230615

Product Description: Clip Sling, Slings Extra Large
Product Code: B-SSPUC-XL
Primary Packaging UDI: 5060405746175
NHSSC Code: FER14255
LOT Number: 230615

Product Description: Clip Sling, Slings Small
Product Code: B-SSPUC-S
Primary Packaging UDI: 5060405746168
NHSSC Code: FER14257
LOT Number: 230715

Product Description: Clip Sling, Slings Medium
Product Code: B-SSPUC-M
Primary Packaging UDI: 5060405746151
NHSSC Code: FER14254
LOT Number: 230715

Product Description: Clip Sling, Slings Extra Large
Product Code: B-SSPUC-XL
Primary Packaging UDI: 5060405746175
NHSSC Code: FER14255
LOT Number: 230715

Product Description: Clip Sling, Slings Medium
Product Code: B-SSPUC-M
Primary Packaging UDI: 5060405746151
NHSSC Code: FER14254
LOT Number: 230730

ATTENTION: Customer, Clinicians, Nursing Staff, Manual Handling Professionals, Risk/Safety Managers, and other users of these devices.

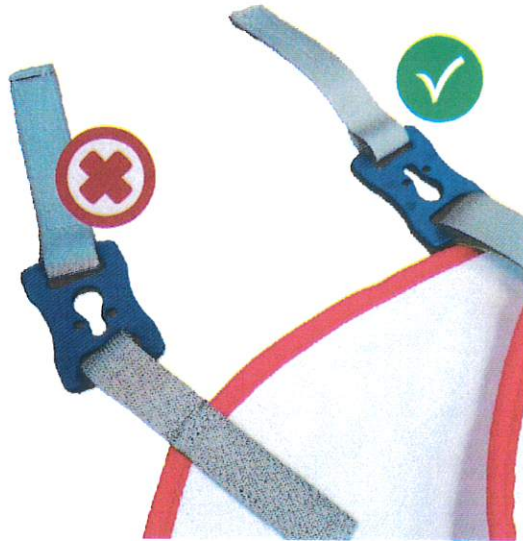
Dear Customer,

As part of our ongoing commitment to patient care, GBUK has initiated a voluntary medical device field safety action for the four affected product LOTs identified above.

Reason for Voluntary Product Field Action:

GBUK has received several complaints regarding the keyhole clasp on the clip sling being assembled incorrectly. This causes the clips which secure the sling to the hoist to face in the wrong direction. This results in the clip not clicking securely in to place and securing the sling to the hoist during use. There have currently been no reported injuries associated with this product fault and it is anticipated that there is a low percentage of slings impacted by this problem. However, as a result, GBUK has taken the decision to voluntary recall

products from the affected LOTS. We can confirm that this does not affect any other LOTS or products that have been placed on the market.



Potential Hazard/Risk to Patient:

Users will potentially be unable to securely attach the clips to the hoist which may result in the patient falling from the sling and potentially sustaining a serious injury.

Clip Sling Direction for Use Wording:

8. Attach the shoulder and leg clips to the spreader bar of the hoist. Ensure that these clips are clicked securely into place.
9. Before operating the hoist, ensure all clips have been secured to the spreader bars.

Required Action:

Any remaining items from any of the LOTS listed above held by you or your customers must be immediately placed in quarantine and taken out of use pending return. This notice must be passed on to all of those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. GBUK will arrange for these items to be collected and either refunded or replaced in due course.

Contact Reference Person:

In case of any questions please contact Melonie Clark, Quality Manager, GBUK, Woodland House, Blackwood Hall Business Park, Blackwood Hall, North Yorkshire, Selby, YO8 5DD.

Melonie.clark@gbukgroup.com; 01757 288587

I can confirm that this notice has been notified to the following:

- MHRA
- SGS UK
- SGS Belgium
- FAMHP in Belgium

Please confirm receipt of this Field Safety Notice by e-mailing back the acknowledgement sheet attached below to the email address above.

On behalf of GBUK we thank you sincerely for your help and support in completing this action and regret any inconvenience this will cause. We would like to reassure you that GBUK is committed to only promoting devices that meet our high internal quality standards and improve patient care.



Chloe Kelly
Head of Compliance

FSCA Acknowledgement Form – GBUK 2023/012/019/601/050

Please complete the following and scan and email to Melonie Clark at Melonie.clark@gbukgroup.com

Check one box as applicable. ✓	
	YES – I confirm receipt and understand this Field Safety Notice and the required actions.
	NO – I do not understand this Field Safety Notice and I would like a representative of GBUK Banana to contact me.

Name:	
Position:	
Hospital/Organisation:	
Address:	
Email Address:	
Date:	

10/2023