

Urgent Field Safety Corrective Notice - MyWay Harness

FSCA-25-02-20

25th February 2020

Attention: Users, customers, carers, parents, therapists, health professional staff and distributors.

Products affected: ALL MYWAY HARNESES

The affected products were manufactured after August 2018.

Product Code	Size	Colour
173-4100-04	1	Green
173-4200-07	2	Purple
173-4300-02	3	Blue
173-4400-09	4	Red
173-4500-06	5	Orange
173-4600-08	6	Grey

Description of the problem:

Through our post-market surveillance activities and returns, we have observed a very small number of isolated complaints relating to a reduction in the adhesiveness of the Velcro on the MyWay harnesses. The MyWay harness consists of two Velcro locking mechanisms. All reported failures relate to the first Velcro strap as detailed in picture A. We have had no recorded incidents where the secondary Velcro strap has failed as highlighted in picture B.

As explained in the user instructions, please ensure that the first Velcro strap (Picture A) is holding firmly before commencing with the use of the product. If either of the Velcro straps is damaged, badly worn or ineffective, then **do not use the product**.

Picture A

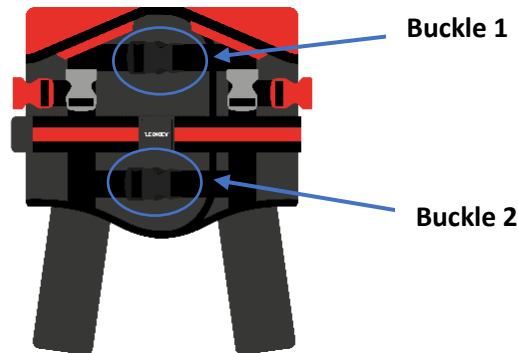


Picture B



Solution to problem:

- Two additional buckles have been added to the harness and the effectiveness of the Velcro has been improved (higher cycle life)
- The revised design has been rigorously tested to prove its efficacy and safety



Advice on action to be taken by the user:

- Continue to use the harness, but pay attention to the status of the Velcro. Conduct daily visual checks of the harness and never use a badly worn harness. In particular, carefully check:
 - the harness and all straps/buckles for signs of wear and tear
 - the Velcro strip and remove any fluff caught in the Velcro hooks to ensure it secures firmly
 - the harness hoisting point and hoisting straps for signs of wear and tear.
- Please complete the enclosed FSCN reply form. If you received the harness and this notification directly from Leckey, please send your completed form, by email, to the contact reference person listed below. If you received this notification from another provider, please follow the advice from your provider on where to send the completed form. On receipt of the form, a new harness will be sent to you. Details on the replacement of your harness will be sent to you either directly from Leckey or from your provider.
- Once you receive this replacement it is essential that you cut through the straps of your old harness and securely dispose of it to ensure this product is no longer used.

Advice on action to be taken by providers/organisations (including action by Distributors):

- **Transmission of this Field Safety Notice:** This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially



affected devices have been transferred / sold. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

- Please ask your end user customers to complete the reply forms and return these directly to you. Once you receive all the necessary reply forms from your end users customers or other organisation, please complete the reply form and indicate that all have received and understood the “Field Safety Corrective Notice.”

Important!

Maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

If in any doubt, please contact our customer service centre on the number below for clarification.

We sincerely apologise for any inconvenience caused by this safety alert.

Contact reference person: Ciaran McKinley
Quality Manager
James Leckey Design Ltd.
19C Ballinderry Road, Lisburn, N. Ireland, UK.
+44 (0)28 9260 0750
ciaran.mckinley@leckey.com

The undersigned confirms that this notice has been forwarded to the appropriate Regulatory Agency

For and on behalf of James Leckey Design Ltd

XXX

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NI Reg No. 23037
VAT Reg No. GB366407149

MD 620777



Field Safety Corrective Notice Reply Form: Response Required

Please complete this form

FSCA-25-02-20

Our records indicate that you have received one or more MyWay Harnesses manufactured from August 2018 onwards. Please fill out and return this **Field Safety Corrective Notice Reply Form**.

1. Do you currently possess any of the affected products?

YES NO

If your harness has moved location please specify the new location below (or indicate if the MyWay accessory is no longer in use):

2. If you are an organisation or distributor please complete this question, otherwise skip to Q3.

Have you further distributed any of the affected products to your customers?

YES NO

If you answered yes, please check this box to confirm that you have notified these customers of the Field Safety Corrective Action.

3. If the answer to question 1 is YES, please list the number of affected products below. We will then send you a replacement harness/harnesses. Please also enter your contact details in the table below, and sign to say that you have received and understood this Field Safety Corrective Notice. Organisations and distributors please respond to this question based on your receipt and understanding of the FSCN and that of your end users.

Product Code	Number of Units	Product Code	Number of Units
173-4100-04 (Size 1- Green)		173-4400-09 (Size 4 – Red)	
173-4200-07 (Size 2 – Purple)		173-4500-06 (Size 5 – Orange)	
173-4300-02 (Size 3 – Blue)		173-4600-08 (Size 6 – Grey)	

Contact Name	
Organisation Name (if applicable)	
Title	
Contact phone No.	
Email address	
Date	
Signature	

Please email this form to fsn@leckey.com or follow the advice of your provider on where to send this form

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