Medifab Limited

Urgent Field Safety Notice

Updated Maintenance Instructions for Shuttle Discovery with 4 Wheel Verve Stroller

Date: 20th September 2019
Medifab Ltd Ref: I03450

Details on affected devices:
Product Code: 2006-0040-000
Device Name: Shuttle Discovery with 4 Wheel Verve Stroller

Attention: End Users, Healthcare Professional Staff, Carers and Parents
Description of the problem:
In the interest of the safety of our customers we would like to highlight a potential safety issue with the folding mechanism on the Shuttle Discovery Stroller.

The folding mechanism on the Verve stroller is controlled by lowering or lifting a lever to lock or unlock the frame. To ensure effective locking is achieved, the tension in the joint must be sufficient, this is provided by a T bolt (shown in yellow circle) and an antivibration nyloc domed nut (shown in orange circle).

Folding lever in locked

Folding joint and antivibration nyloc domed nut.

The product has been tested to withstand the expected vibrations in use. However, due to the variable nature of where and how the product can be used, a gap may develop over time at the folding joint which can be easily corrected by tightening the antivibration nut during routine maintenance.

If the antivibration nut is overtightened, it will damage the T bolt within the folding joint which will lead to a greater gap at the folding joint. This could provide a finger entrapment for the user and anyone interacting with the frame, potentially leading to serious injury,

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Manufacturer of spex

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We have been notified of an incident where the T bolt has been damaged due to overtightening of the nyloc nut leading to a serious injury to a user.

In view of this incident we have updated the six-monthly checks, within the maintenance section of our IFU (Instruction for Use), to give clearer information regarding the maintenance of the folding joint assembly and the importance of tightening the Nyloc nut correctly.

Medifab has reviewed the User Instructions and have published an enhanced User Manual.
A copy of the amended User Manual can be downloaded from Medifab's website:
https://www.medifab.co.nz/products/strollers-pushchairs/spex-discovery

Advice on action to be taken:
Without a child or seat in the stroller frame and with the joint locked, check your frame for movement in the folding joint. If there is a gap greater than 2mm is present at the folding joint, please check the T bolt has not been damaged.

If the plastic shroud covering the head of the T bolt is broken or missing please stop using the product and contact your Shuttle Discovery distributor, health care provider or Medifab to arrange the fitting of a replacement T bolt.

If the T bolt is not damaged follow the maintenance guidance provided in our updated User Manual on our website to tighten the nyloc domed nut.
https://www.medifab.co.nz/products/strollers-pushchairs/spex-discovery

Damaged T-Bolt The metal section of the T bolt is exposed and appears bent

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and / or any organisation where the potentially affected devices have been transferred. Please complete the attached Acknowledgement Form within 10 business days of receipt of this letter and return it to solutions@medifab.com
Please also ensure that awareness is maintained for an appropriate period.

Medifab would like to thank you for your cooperation, understanding and your support and we apologise for causing any inconvenience.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

Stuart Clook
Quality & Regulatory Affairs Manager
DDI +64 (0) 3 307 9907 Email: stuart.clook@medifab.com

Medifab confirm that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.

Reply Form
Field Safety Corrective Action – I03450

Action Completed	**Please tick to** confirm that the necessary corrective action, as documented in this Field Safety Notice I03450 has been receipted and acted upon.
Receipt of Field Safety Notice	

Action Completed

Signed……

Company
(if applicable) ……..

Email: ……..

Date……

Please scan and email form back to Medifab office at : solutions@medifab.com
Reply forms can also be posted or faxed to our Head Office address below.

For the attention of:
Quality & Regulatory affairs Manager
Medifab Ltd

You have a responsibility under the Medical Device Directive to notify the manufacturer when corrective actions have been completed.

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