

James Leckey Design Limited
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Urgent Field Safety Notice - Firefly Floorsitter Medical Device Correction

FSCA-23-09-19

23rd September 2019

Attention:

End users including carers, parents, health professional staff, and distribution partners.

Products affected:

Firefly floorsitters supplied before 31st January 2018 are affected. This impacts the following products:

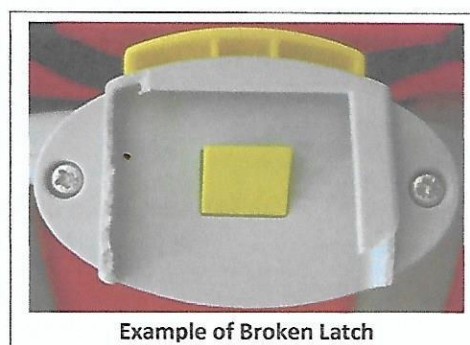
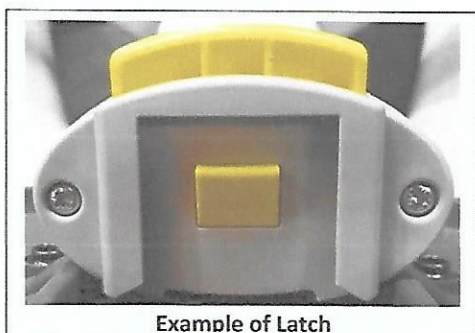
Product Name	Product Code	Serial Number Range	Date of Manufacture
Firefly Splashy	All codes beginning 176	LEC/178486 to LEC/206637	1 st November 2016 to 31 st January 2018
Firefly GoTo Seat	All codes beginning 167 and including letter 'F' in code	LEC/189092 to LEC/204087	1 st May 2017 to 31 st January 2018

Description of the problem:

The Splashy bath seat and the GoTo seat are attached to a height adjustable Floorsitter with two latches which click into position. One latch is located on the Floorsitter base, whilst the second latch is located on the recline arm of the Floorsitter.

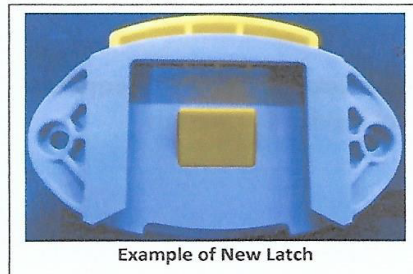
We have received reports of a number of broken latches on the floorsitter. Such a breakage could cause the back of the seat to collapse rapidly. Any reported breakages have been followed up, and no injuries have been reported.

However, whilst the risk of occurrence is remote, such an occurrence could cause a serious injury. In the interest of user safety, we have decided to perform a Field Safety Corrective Action.



Solution to problem:

We have identified a solution which should eliminate the risk of further similar incidents. This involves replacing both latches on the Floorsitter with an improved, much more robust design. The new design has been tested, and the new parts will be sent to all affected customers, along with simple retro-fit instructions, during October 2019.

**Transmission of this Field Safety Notice (including action by Distributors):**

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.

Important! REPLY FORM

Please complete the attached form to confirm the successful completion of this Firefly Floorsitter "Field Safety Notice" by stating the serial number(s) on the return information form and returning it to contact reference person listed below

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:

Ian Latimer
Head of Sales & Business Development, Firefly by Leckey
19C Ballinderry Road, Lisburn, N. Ireland, UK.
+44 (0)28 9260 0750, [REDACTED]

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

For and on behalf of James Leckey Design Ltd [REDACTED]

Ian Latimer, Head of Sales & Business Development, Firefly by Leckey

CC to:

1. Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities