
Urgent Field Safety Notice

Commercial name of the affected products: Eleganza 2

FSCA-identifier (assigned by manufacturer) : V217

Type of action: Safety information to medical device users in all healthcare areas

Date: December 3, 2018

Attention: Based on feedback from the field the Linet spol. s r.o., as responsible manufacturer, decides to highlight users of Eleganza 2 hospital beds about potential risk of cracked welding on Eleganza 2 plastic siderails in Kingdom of Saudi Arabia (KSA).

Details on affected devices:

Type of product	Electrically operated hospital bed
Commercial name of product	Eleganza 2
Model number:	1GRA
List of affected orders:	VZ/2016/587, VZ/2016/663, VZ/2017/121, VZ/2017/169, VZ/2017/271, VZ/2017/340, VZ/2017/399

Description of the problem:

The material used during the time of production of KSA orders of new beds showed sufficient firmness of the siderail and minimal required firmness of the weld. Based on the reported cases in KSA we have revealed that the siderails and bed end may crack at critical spot of the weld during the standard use. The Risk assesment evaluated all risks for users as low.

The instruction of use of the affected model already warns that using defected beds is not allowed and contacting the manufacturer or service organization immediately is requested.

Advise on action to be taken by the user:

No needed action to be taken by the user. The service partner of the manufacturer in KSA will contact all hospitals with above mentioned hospital bed model and will organize the preventive checks of the beds in the hospitals.

If your facility finds cracked siderail before the preventive action will be taken, please contact manufacturer or service organization. Priority will be assigned respectively.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

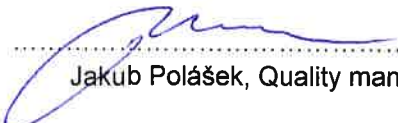
Contact reference person: Eng. Akram Abu Elgasim, Salehiya Trading Company, Abdullah Suliman Al Hamdan Street, 11421 Riyadh, telephone number: +966 0114646955- Ext. 966, email: a.abuelgasim@salehiya.com.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please contact Linet representative directly or via above mentioned telephone number with any questions related to this Urgent Field Safety Notice.

An acknowledgement form for the receiver is supplied with this Field Safety Notice to confirm the customer was informed and understands.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

On behalf of Linet spol. s r.o.:

A handwritten signature in blue ink, appearing to read 'Jakub Polášek', written over a horizontal dotted line.

Jakub Polášek, Quality manager