

**Notice Information: - Advisory
12 August 2011**

Part 1. Product Information

- a) Title: Linet Eleganza Standard and Deluxe Model Bedframes
- b) Product Name/Type: Linet Eleganza Standard and Deluxe Model Bedframes
- c) Reference: SN2011(20)
- d) Manufacturer/Supplier: Linet Spol s.r.o. Czech Republic

Part 2. Target Audience

- a) Target Audience:
- Hospital Managers / CEOs
 - Clinical Directors
 - Risk Managers
 - Purchasing Managers
 - Nursing Managers
 - Paediatric Ward Sisters
 - Health Services Executive (HSE)
 - Public and Private Nursing Homes
 - Theatre and Nursing Staff
 - Medical Device Distributors
 - Clinical / Biomedical Engineers

Part 3. Problem/Issue

- a) Problem/Issue: Linet has become aware that certain bedframes are susceptible to developing cracked or damaged welds in one particular area of the bedframe.

Part 4. Background Information

a) Background Information:

Linet has determined that the fault is related to a sporadic occurrence of cracking or breaking welds connecting the patient surface (frame) to the main lifting column assembly. The two column assemblies are connected to the frame, each by two brackets. The cause of the damage is possible vibration during transport or stressing of the device during possible overloading conditions experienced over time.

Linet has published a field safety notice (FSN, see attached) and has developed a field modification to address this issue.

Part 5. Action to be taken

a) Action to be taken:

Linet has confirmed that this issue is confined to bedframes manufactured up to December 2005 (see FSN for affected serial numbers). To date, Linet has been unable to obtain full traceability for affected devices potentially distributed in Ireland.

The IMB advises that users:

- Identify the affected devices in your facility.
- If you have affected devices, follow the manufacturer's recommendations, as outlined in the attached FSN, and contact Linet to arrange for modification.

Part 6. Enquiries

a) All enquiries should be made to:

Enquiries to Linet should be addressed to:

Rowena King / Richard Westbrook

Linet UK Service Department

Linet House

17 Murrills Estate

Portchester

Hampshire

PO16 9RD

United Kingdom

Telephone: +44 2392 322135 / +44 2392 322134

Fax: +44 2392 389540

E-mail: rking@linet.uk.com , rwestbrook@linet.uk.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033 E-mail: vigilance@imb.ie Website: www.imb.ie

Please

E-mail: vigilance@imb.ie

Website: www.imb.ie

Please click here to download PDF version of [safety notice](#)

Please click here to download PDF version of [field safety notice](#)