

[Issue 6]

Sling & Hoist Compatibility Statement

Since 1993, Silvalea has manufactured patient lifting slings and manual handling products for lift manufacturers worldwide. Interchangeable slings have been an issue for many healthcare professionals, however with a full risk assessment, conducted by a competent assessor, the use of interchangeable slings could provide a solution for the patient.

Guidance on risk assessments and competency can be found from your country specific health & safety regulators. For example, in the UK guidance can be found under the UK's Provision and Use of Work Equipment Regulations 1998 (PUWER) which falls under the guidance of the Health & Safety Executive (HSE).

- Silvalea governs its own research, design and manufacturing following the guidelines and testing requirements set out in ISO 10535:2006 Hoists for the Transfer of Disabled Persons: Testing Requirements.
- All design and testing information is electronically documented and stored so that we can swiftly meet our obligation to release information if and when requested, to any governing body such as the UK Medicines and Healthcare Products Regulatory Agency (MHRA), Health Canada and any other governing body or regulatory authority.
- Silvalea is self-regulated using the ISO 9001:2015 and ISO 10535:2006 quality control systems. Certification number is FM35946.
- All products, where applicable and following guidelines laid out by the UK MHRA under the Medical Devices Directive 93/42/EEC (2002), carry a CE mark and from 2021 will also carry a CA mark for products in use within the UK. Certification number is 224
- Silvalea products are classified as a Class 1 Medical Device in both the UK and Canada.
- Silvalea products fall under the GMDN (Global Medical Device Nomenclature) database.
- GS1 labelling is available. Company prefix number is 50563874.
- Silvalea is registered with the Food & Drug Administration within the US. Certification number is 3008720499.
- Unique Device Identification (UDI) Protocol is a worldwide system to help improve the identification of medical devices, to ensure the identity of the manufacturer or distributor of medical devices, along with ensuring the product details are clearly identifiable.

These measures have been introduced to improve end user safety and reduce accidents with clear concise labelling requirements. These changes are ongoing and will in time be adopted by the UK MHRA and US FDA.

Silvalea takes responsibility to uphold the protocols ensuring that their distributors, contractors, healthcare providers and end users receive products clearly labelled, safe and fit for purpose.

Guided by the UK Lifting Operations and Lifting Equipment Regulations 1998 (LOLER), we ensure that each product is clearly labelled with the product design, compatibility with spreader bar type, safe working load and washing instructions.

LOLER sets out specific UK instructions to visibly check each sling or lifting device before each use for general wear and tear. In addition, the guidelines set out at least one robust thorough test by a competent person every $\boldsymbol{6}$

In other regions this robust test is usually carried out annually in line with localised hoist and other lifting equipment regulations.

All Silvalea slings carry a unique service label for quick and easy identification of 6-monthly or annual sling checks.

If you are in any doubt on safety or integrity of a lifting device it must be withdrawn from use immediately. These guidelines are clearly laid out in our instructions of use.

Silvalea conducts regular research on many leading hoist manufacturers products to ensure compliance and compatibility. A full list of tested hoists is available below and should be discussed with a member of our technical team if any doubt arises.

The interchangeability of Silvalea slings across different lift manufacturers should NOT BE ASSUMED. A full risk assessment must always be conducted by a competent assessor.

A sling should always be used in conjunction with its instructions of use and compatibility is dependent on the lift type. For example, a 2-point loop fixing spreader bar is for those slings with loop attachments (or Silva Slot® within the UK, Australian and European markets) and a stud (wishbone style) spreader bar is for clip slings only.



spanamerica.com Silvalea slings are distributed in North America by Span (USA: Span-America Medical Systems, Inc, Canada: Span-Canada Medical Products LP). Span America: 70 Commerce Center, Greenville, SC 29615

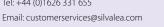


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savaria.com Silvalea Ltd, Span-America Medical Systems, and Span-Canada Medical Products LP are divisions of Savaria Corporation. For more information about Savaria patient lifts: patient-lifts.com







Useful Points when Ordering Replacement Slings

Silvalea Ltd conduct regular research and testing to ensure that Silvalea Ltd replacement slings meet with the requirements necessary of the major leading hoists within the market. The manufacturers of these hoists are listed below at the time of printing, changes are reserved.

The consideration of the list below does not absolve the nursing staff from the obligation to assess each transfer situation under the safety aspect, to check, whether the sling is appropriate with regards to the size and type for the patient, and to conduct a risk analysis of the sling and hoist combination.

Slings with Clips are compatible with hoists having 4 point stud fixing spreader bar by the following production companies	Limitations:
Allegro	
Arjo Huntleigh GmbH	
Beka Hospitec GmbH	
Helping Hands	
Horcher GmbH	
Huntleigh (HNE)	
Joerns Healthcare LLC	
Meden-Inmed	
OpeMed	
Oxford	
Promed	
RMT RehaMed Technology GmbH	
Spectra Group	

Slings with loops are compatible with hoists having a 2, 4 or 6 point loop fixing spreader bar and an 8 point for Stretcher type styles, by the following production companies	Limitations:
AKS GmbH	
Allegro	
Arjo Huntleigh GmbH	
Ato Form GmbH	
Beka Hospitec GmbH	
BHM Medical Inc.	
Braus Lift & Care Systems GmbH	
Caricare Nopac	
Carters Invacare	
Chiltern Invadex	
DaysHealthcare (DMA)	
Doherty	
Ergolet	
Etac GmbH	
Faaborg Rehab Technic	
Freeway	
Georg Krämer	
Guldmann GmbH	
Handicare	
Handi-Move	
Helping Hands	
Hill Rom Inc.	



...List Continued



Horcher GmbH	
Hoyer GmbH	
Huntleigh (HNE)	
Invacare GmbH	
J. Böhm GmbH	
Joerns Healthcare	
Liftech	
Liko	
Locomotor	
Meden-Inmed	
MEYRA GmbH	
Molift	Not suitable with Molift Quick Raiser 205, Molift Quick Raiser 1 and 2
Moorcare	
Nopac	
Nausicaa Medical	
Nordic Care	
Nordic Rehab AB	
novacare GmbH	
OpeMed	
Osprey	
Oxford	
Park-Lite Range	
Prism	
Promed	
RMT RehaMed Technology GmbH	
Rebotec Rehabilitationsmittel GmbH	
Romedic	
Ropox	
Savaria	
Span-America	
Spectra Group	
Talley	
Taylors	
TRanspoRehaMed GmbH	
Trautwein GmbH	
Vassilli Srl.	
Weiner Innovative Medizintechnik (Lifter Omnilift)	
Wessex	
Westholme	

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