<<Customer>>
<<Salutation>>
<<Street, Nr.>>
<<address supplement>>
<<Postcode, Town>>
<<Country>>

Field Safety Notice – FSN 01/2025

Replacement of hand control

for

LISA LE therapy and nursing bed (LE = low entrance)

Your customer number: <<Customer-Nr.>>

Osnabrück, 26 November 2025

Sender:
FreiStil Tischlerei GmbH & Co. KG, Ruppenkampstr. 16, 49084 Osnabrück, Germany; SRN: DE-MF-000009449

Addressee:
Specialist dealers, users and operators

Identification of the affected medical devices:
LISA LE (LE = low entrance) therapy and nursing beds without anti-entrapment protection (see attached bed list)

Description of the problem, including the identified cause:

Dear Sir or Madam,

As part of our ongoing market monitoring, we became aware of an fileld safety notice from a competitor informing us of a serious incident involving one of its beds.

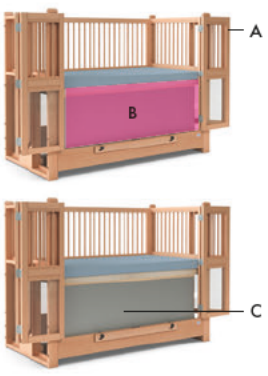
The problem described in the notice was as follows: *'If the adjustment functions of the hand control are not locked with a key when patients (children) are unattended, there is an increased risk that the patient (child) or third parties (children) may operate the hand switch and trap themselves or others under the lying surface or between the adjustable elements of the lying surface. This can lead to serious injuries or even death of the patient (child) or third parties (children).'*

The cause determined was as follows: 'The occurrence of the risk is solely attributable to human error.'

Our view of the issue: The competitor's product in question is a bed that is similar to our LISA (**A**) bed. Specifically, the issue at hand concerns the area where there is an increased risk of entrapment, namely the space (**B**) underneath the lying surface that is created when the bed is raised.

When we began developing our therapy and care beds (around 2002), we at FreiStil were determined to avoid pinch points and trapping hazards in the area of the lying surface height adjustment. We therefore developed our anti-entrapment guard (**C**), which automatically closes the space under the lying surface in the bed base as soon as the lying surface is raised. In conjunction with the lockable hand control, this anti-entrapment guard (**C**) provides an additional integrated safety feature that has always effectively prevented human error.

Our LISA models and our other bed series LEA, LUKAS and LEON, in which the lying surface also moves in the bed base, have always been equipped with an anti-entrapment device (**C**) as standard.

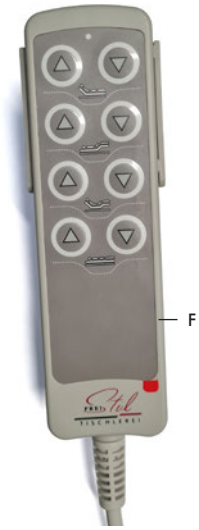


Only a small part of our LISA bed series, the LISA LE models (LE = low entrance, see **D+E**), did not have this additional safety feature until the end of 2024. As the LISA LE models on the market, which do not have anti-entrapment protection, also pose an increased risk of entrapment for unsupervised users if the hand controls are not locked, we decided at the end of 2024, as part of our risk management, to change the configuration options for these models so that, since January 2025, they have only been available with anti-entrapment protection.

Based on new market insights and current technical possibilities, we have also worked with our supplier to further develop our hand control in line with the concept of integrated safety. In future, this will feature an automatic shut-off function that will automatically switch off the hand control after 10 seconds of inactivity.

What measures must be taken by the addressee?

As a corrective action, we will immediately arrange for the replacement of these controls on all LISA LE beds without anti-entrapment protection on the market as soon as we receive the new hand controls with automatic shut-off (**F**) at the beginning of the second quarter of 2026.



Please note that LISA LE beds without anti-entrapment protection delivered before July 2017 contain system components that are not compatible with the new hand control. Even though these beds have already exceeded the 7-year service life specified by us, we would still like to offer you the opportunity to upgrade these beds to the latest standard in a sustainable and cost-effective manner compared to purchasing new equipment. The prerequisite for this is that the bed in question has been regularly serviced in accordance with our specifications and has been certified as still suitable and safe for its intended purpose.

In order to prepare the corrective action optimally, we require feedback from you for each bed:

For beds equipped with old system components

- whether it has already been taken out of service
- whether an offer to replace the system components (including new hand controls) is desired
- whether it will be taken out of service
- whether it is no longer accessible (including information on its further whereabouts)

If, for specific reasons, conversion is not desired, a new supply must be provided immediately and the bed in question must then be taken out of service and disposed of.

For beds where the hand control should be replaced

- whether it has already been taken out of service
- whether a new hand control should be sent
- whether it is no longer accessible (including information on its further whereabouts)

Please complete the attached response form, including the bed list, and return it to us by 31 December 2025.

To ensure the continued safe use of LISA LE beds until the corrective action has been implemented, we kindly ask you to inform the respective users of these beds of the following safety instructions:

- DANGER: Ensure that no one ever gains access to the bed base underneath the lying surface and that no objects ever fall into it. There is a risk of CRUSHING/DEATH.
- DANGER: Ensure that no parts of the body are in or under moving parts. There is a risk of CRUSHING/DEATH.
- DANGER: When not in use, the hand control must always be locked and placed outside, out of reach of the user, together with the cable There is a risk of CRUSHING/STRANGULATION.
- CAUTION: Please note that the lowest horizontal position of the lying surface is the safest – especially when the user is unattended! Only this position should be used unless another position is necessary for therapy or care applications. After use, the lying surface must always be lowered to the lowest position and the revolving doors must be locked.

For your external communication, we are providing you with separate safety information to pass on to users.

Dissemination of the information described here:

Please ensure that all users of the above-mentioned products and other persons who need to be informed within your organisation are made aware of this field safety notice. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please retain this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) in Germany has received a copy of this 'Urgent Safety Information'.

Contact person:

FreiStil Tischlerei GmbH & Co. KG
Thomas Zander (Managing Partner, PRRC)
Fon: +49 (0)541/800 3969 0
E-Mail: qm@freistil.com

We would like to conclude by pointing out that the upcoming replacement of the hand control or the possible retrofitting of system components, including the new hand control, is a precautionary action to increase user safety and is not based on any incident involving one of our products. The safety of our mutual customers is very important to us, and we would therefore like to thank you in advance for your support and understanding.

If you have any questions, please do not hesitate to contact us.

Your FreiStil-Team

Attachments:

- Response form including bed list
- Urgent safety information for users