Thuasne Deutschland GmbH · Im Steinkamp 12 · D-30938 Burgwedel

27.11.2023

Field Safety Corrective Action for Class I Medical Devices

SpryStep Custom AFO, SpryStep Vector AFO, and SpryStep Vector KAFO

Dear Thuasne Customer/Distributor,

(1) Purpose of this letter

The purpose of this letter is to advise you that Thuasne Deutschland GmbH in its role as Legal Manufacturer is implementing a voluntary Field Safety Corrective Action for Custom Made products,

- SpryStep Custom Ankle-Foot Orthosis (AFO)
- SpryStep Vector AFO, and
- SpryStep Vector Knee-Ankle-Foot Orthosis (KAFO),

intended for treatment of biomechanical deficits.

No serious injuries and/or deaths have occurred due to the failure mode associated with this measure.

www.thuasne.de

Headquarter/Production site
Im Steinkamp 12
D-30938 Burgwedel
Tel.: +49 5139 988-0
Fax: +49 5139 988-177

Production site:
Hauptstraße 16
D-35099 Burgwald
Tel.: +49 6451 7212-180
Fax: +49 6451 7212-980

Customer service standard order:
Tel.: +49 5139 988-205
Fax: +49 5139 988-177
kundenservice@thuasne.de

customer service made to measure:
Tel.: +49 6451 7212-180
Fax: +49 6451 7212-980
massbestellung@thuasne.de

(2) Reason for the measure

The reason for the corrective action is due to a complete strut breakage, as shown in the picture below. We received reports of a small number of braces with a complete strut breakage either upon examination by clinician at initial receipt, during patient application, or shortly thereafter.

Frequency of failures and complaints - We are aware of a 2.9% failure rate related to this issue, whereas 97.1% of the product are functioning as designed.

(3) Risk to Health

Due to a vacuum system leak, there is the possibility that air pockets exist between the layers of material that may cause the strut to completely break or fracture, resulting in a potential loss of balance and/or potential of a fall.

The device failure is due to possible air pockets in the strut, resulting in breakage. This might be observed at initial receipt, during patient application, or shortly thereafter.

(4) Customer/User Actions

The safe handling of the recalled product should be implemented per below:

- Clinician / CPO should contact any patient who was fit with a device received between June 14th and September 10, 2023, to notify them of the recall and schedule a visit to examine the patient's device.
- During the patient visit, the clinician / CPO should examine the device for structural defects (delamination, cracking, complete breakage, etc.) in the area identified in the picture above in Section 3.
- If the device is observed with a defect, patient should immediately discontinue use of the device and it should be returned to THUASNE BENELUX, Customer Service, Klompenmaker 1-3, 3861 SK Nijkerk, The Netherlands.
- If the device is observed with a defect, patient should immediately discontinue use of the device and it should be returned to Thuasne. While waiting for a replacement device, advise the patient to utilize their previous orthosis. If they do not have one, recommend the use of walking aids.
- Clinician / CPO can contact THUASNE BENELUX, Customer Service, Klompenmaker 1-3, 3861 SK Nijkerk, The Netherlands, +31 (0) 33 2474444, for return and replacement instructions.
- THUASNE BENELUX will either refund or replace the product.
- Clinician / CPO to complete and return the attached Acknowledgement and Receipt Form within 5 working days.

(5) Product and Distribution Information

U3300, batch 33584182 (sold in NL)
U3300, batch 33411065 (sold in BE)
U3300, batch 33411130 (sold in BE)

(6) Type of Action by the Company

Thuasne implemented the following corrective and preventive actions for this issue:

Immediate corrective actions:

- Eliminated leaks in vacuum system.
- Conducted 100% inspection of finished products.

Long-term preventive actions:

- Verify and document the vacuum system is continuing to function properly by conducting a daily drop-test.
- Continue conducting the 100% inspection of finished products.

(7) OTHER INFORMATION

This information was prepared by:

DocuSigned by:
Joachim Dehmel
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27. November 2023 | 15:32:48 MEZ

Joachim Dehmel
CEO Thuasne Deutschland GmbH

DocuSigned by:
Tjark Siedentop
E97AA702A1A145C...
27. November 2023 | 15:18:08 MEZ

Dr. Tjark Siedentop
Director R&D / Operations / QM-RA
Person responsible for regulatory compliance acc. to Article 15 MDR

THUASNE Deutschland GmbH
Field Safety Corrective Action Return Response Acknowledgement and Receipt Form

Response is Required

Customer Information:

Customer Name: _____

Street Address: _____

City, State, Zip Code: _____

SpryStep Custom AFO, SpryStep Vector AFO, and SpryStep Vector KAFO

I have read and understand the recall instructions provided in the Nov. 27, 2023, letter.

Yes ___ No___

Any adverse events associated with recalled product? Yes ___ No ___

If yes, please explain:

_____

_____

_____

_____

Under separate cover, we will provide you with a list of orders affected by this recall notice.

Return Response Box:

Please provide the following information regarding the product:

1. Number of patients seen: _____
2. Patient ID or initials: _____

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3. Product Code: _____
4. Device breakage? Yes ___ No___

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE EMAIL OR FAX COMPLETED RESPONSE FORM TO:

Email: Thuasne Deutschland GmbH Quality Management / Regulatory Affairs

ra@thuasne.de

OR MAIL TO:

Thuasne Deutschland GmbH
Dr. Tjark Siedentop / Christine Graß
Im Steinkamp 12
D-30938 Burgwedel
Germany