FSN Ref.: R-2023-03
24.04.2023

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Device Commercial Name:

LinkSymphoKnee System, L-Shaped Femoral Augment Medial-Right/Lateral-Left, Size 5-6 Tilastan, cemented, H= 15 mm

REF MAT Tilastan*	Size	Side	Height mm
880-325/13	5-6	Medial-Right/Lateral-Left	15

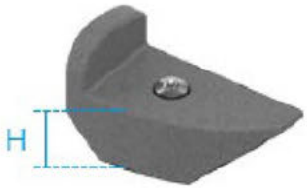

Figure 1: REF: 880-325/13 LOT: 1910003 – incorrect orientation

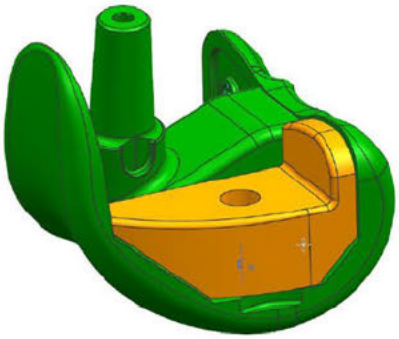

Figure 2: example image with correct orientation

For Attention of*:

☒ Distributor / Local branch of manufacturer
☒ Hospital

Contact details of local representative*:

Responsible Person (Deputy)
[redacted]
Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany
E-Mail: vigilance@link-ortho.com
Tel. +49 (0)40 5 39 95 432

Risk addressed by FSN

1. Information on Affected Device

1.1 Device Type*:

L-Shaped Femoral Augment

1.2 Commercial name:

LinkSymphoKnee System, L-Shaped Femoral Augment Medial-Right/Lateral-Left, Size 5-6 Tilastan, cemented, H= 15 mm

1.3 Unique Device Identifier (EU UDI-DI):

04026575258123

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable LinkSymphoKnee manufactured by Waldemar Link GmbH & Co. KG is intended for long-term replacement of a diseased and / or defective knee joint in the human body. The knee system forms a total replacement of the knee joint consisting of femoral and tibial metal components which are connected by a polyethylene plateau. The LinkSymphoKnee can be used with full-grown, anesthetized patients of any ethnic origin and sex. The LinkSymphoKnee can be implanted with and without cement. The implants may only be used and operated in an aseptic medical environment by persons who have the required training, knowledge and experience in the orthopaedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.

The LinkSymphoKnee features a variety of different femoral augments offering a variety of augmentation options to compensate for distal and/or posterior femoral bone deficiencies. The femoral augments can be used in conjunction with the modular femoral components (CCK/Revision).

1.5 Article number(s)*:

880-325/13

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

1910003

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

Due to a complaint, it has come to our attention that one production order of 20 LinkSymphoKnee L-Shaped Femoral Augments (REF 880-325/13) does not contain the correct implant in the packaging. The packaging incorrectly contains the opposite side of the implant (Lateral-Right/Medial-Left instead of Medial-Right/Lateral-Left).

2.2 Hazard giving rise to the FSCA*:

Prolongation of surgery due to intraoperative change in procedure.

2.3 Probability of problem arising:

The occurrence of failure is almost certain.

2.4 Predicted risk to patient/users:

See 2.2

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

Waldemar Link received one complaint regarding this error pattern.

2.7 Other information relevant to FSCA:

To date, no further complaints have been registered regarding this error pattern.

3. Type of action to mitigate the risk

3.1 Action to be taken by user*:

☒ Identify Device
☒ Quarantine Device
☒ Return Device
☐ Destroy Device
☐ On-site device modification / inspection
☐ Follow patient management recommendations
☐ Take note of amendment / reinforcement of Instructions For Use (IFU)
☐ Other
☐ None

- Should you have any of the affected product in your inventory, please send the products back to Waldemar Link GmbH & Co. KG.
- Replacement will not incur any costs to you. Should you have any question on acquiring replacements for forthcoming surgeries, please contact your local sales representative or customer service for Link products.
- We would be grateful if you could return the reply-form to us in any event until the **08.05.2023** as documentation of the recall. This applies even if you have none of the listed products in stock or if these products do not exhibit the defect in question.

3.2 By when should the action be completed ?:

15.05.2023

3.3 Particular considerations for implantable device: Is follow-up of patients or review of patients' previous results recommended ?

It is obvious that this is an incorrect Femoral Augment. If it has nevertheless already been implanted by mistake, we recommend continuing with the regular follow-up care.

3.4 Is customer Reply Required ?* :

☒ Yes, until: 08.05.2023 ☐ No

3.5 Action being taken by the manufacturer

- ☒ Product Removal
- ☐ On-site device modification / inspection
- ☐ Software upgrade
- ☐ IFU or labelling change
- ☐ Other
- ☐ None

3.6 By when should the action be completed ?

01.06.2023

3.7 Is the FSN required to be communicated to the patient /lay user ?

☐ Yes ☒ No ☐ N/A

3.8 If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet ?

- ☐ appended to this FSN
- ☐ not appended to this FSN

4. General Information

4.1 FSN Type*:

☒ New ☐ Update

4.2 For updated FSN

Reference number of previous FSN:
Date of previous FSN:

4.3 For updated FSN, key new information as follows:

N/A

4.4 Further advice or information already expected in follow-up FSN ?*:

☐ Yes ☒ No ☐ not planned yet

4.5 If follow-up FSN expected, what is the further advice expected to relate to ?:

N/A

4.6 Anticipated timescale for follow-up FSN:

N/A

4.7 Manufacturer information:

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany
https://www.link-ortho.com/
Single Registration Number (EU SRN-No.): DE-MF-000005215

4.8 The Competent (Regulatory) Authority of your country (EU) has been informed about this communication to customers. *:

☒ Yes ☐ No

4.9 List of attachments/appendices:

N/A

4.10 Name/Signature:

[redacted]

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. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.