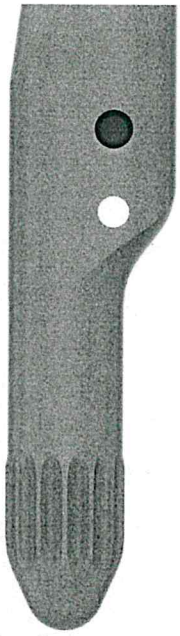
FSN Ref.: R-2025-01
14.02.2025

URGENT FIELD SAFETY NOTICE – Product Recall / Advisory Notice

Device Commercial Name:

LinkSymphoKnee - Modular Stem cylindrical, Tilastan, press-fit cementless, L= 80 mm



Modular Stem with offset

Modular Stem without offset

For Attention of*:

☒ Distributor / Local branch of manufacturer
☒ Hospital

Contact details of local representative*:

Waldemar Link GmbH & Co. KG
Responsible Person
Dr. Poroshat Khalilpour
Barkhausenweg 10
22339 Hamburg, Germany
E-Mail: vigilance@link-ortho.com
Tel. +49 (0)40 5 39 95 707

Risk addressed by FSN

1. Information on Affected Device

1.1 Device Type*:

LinkSymphoKnee

1.2 Commercial name:

Modular Stem cylindrical, Tilastan®, press-fit cementless, L= 80 mm, Ø 11 mm
Modular Stem cylindrical, Tilastan®, press-fit cementless, L= 80 mm, Ø 12 mm
Modular Stem cylindrical, Tilastan®, press-fit cementless, L= 80 mm, Ø 13 mm

1.3 Unique Device Identifier (EU UDI-DI):

04026575443925
04026575443932
04026575443949

1.4 Primary clinical purpose of device*:

The LinkSymphoKnee is a mechanical reconstruction of the knee joint.

The LinkSymphoKnee is a bicondylar knee joint prosthesis which is available in different configurations allowing either posterior cruciate ligament retaining (CR) or posterior cruciate substituting (PS/PS+) procedures. On top, the system also includes a condylar constraint (CCK) configuration. The LinkSymphoKnee consists of femoral components, articulating surfaces, tibial components and patella resurfacing components. The PS configuration includes the additional option of an All-Poly tibial component. Both the femoral and the tibial components are available in a monoblock and a modular version. In addition, there is a selection of femoral and tibial stems and augments, which can be used in conjunction with the modular version of the femoral and tibial components. The modular versions have a taper connection, allowing for the assembly of various tibial and femoral stem extensions as well as the addition of augments.

The system comes in different sizes for femur and tibia and different sizes and heights for the articulating surfaces.

1.5 Article number(s)*:

Artikel REF	LOT Nr.
880-601/11	1943294
	1943296
	1943297
	2049174
880-601/12	1943274
	1943276
	2049172
	2049173
	2049175
880-601/13	1943277
	1943280

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

See point 1.5

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, a problem was discovered during the scanning process of the label at the customer's site. The reason for this problem was a duplicate GTIN on the label. According to the master database, the GTIN should be 0426575443932, but the GTIN on the affected product label is 04026575261611. During the investigation two further articles with a duplicate GTIN could be detected.

2.2 Hazard giving rise to the FSCA*:

It is unlikely that the error of a duplicated GTIN will have any impact on the patient.

2.3 Probability of problem arising:

The probability of harm to the patient is classified as unlikely. All important information related to the product is correctly indicated on the label and on the implant itself.

2.4 Predicted risk to patient/users:

The severity of patient harm is classified as serious in terms of planning a revision and traceability due to the duplicated GTIN, referring to a different article. The severity could be significantly reduced if the article number is used instead of GTIN.

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

One complaint was received regarding this issue.

2.7 Other information relevant to FSCA:

N/A

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.
- Please return the reply form to us in any event until the **28.02.2025** 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?:

28.02.2025

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

☐ Yes, the following:
☒ No, because: All important information related to the product is correctly indicated on the label and on the implant itself, therewith it can be assumed that the correct implant had been implanted.

3.4 Is customer Reply Required?*:

☒ Yes, until: 28.02.2025 ☐ 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?

01.04.2025

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 REF (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:

Paroshat Khalilpour

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.