FSN Ref.: R-2025-05
28.07.2025

URGENT FIELD SAFETY NOTICE – Product Recall / Advisory Notice

Device Commercial Name:

LinkSymphoKnee System, Tibial Component, Modular, Symmetric, Sz. 5, CoCrMo/TiNbN, cemented, Fixed:

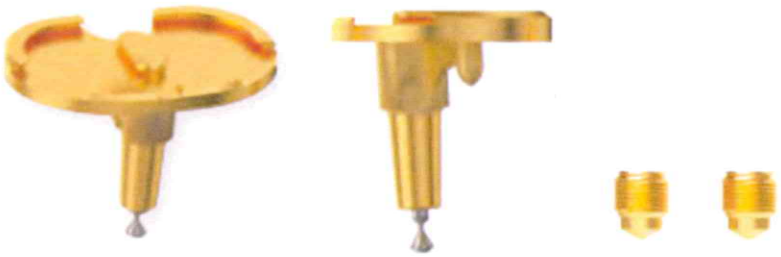

Figure 1: Example images - LinkSymphoKnee TiNbN Tibial component, modular with security screws

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, Tibial Component, Modular

1.2 Commercial name:

LinkSymphoKnee, Tibial Component, Modular, Symmetric, Sz. 5, CoCrMo/TiNbN, cemented, Fixed

1.3 Unique Device Identifier (EU UDI-DI):

04026575251278

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 when combined with the femoral-, tibial- and 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 people 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.
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. All femoral and tibial metal components are offered with PorEx (TiNbN) surface modification. The PorEx coating is a ceramic-like surface modification and reduces the release of ions by up to 90 % (measured in static condition).

1.5 Article number(s)*:

880-100/50

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

210125/2259 210125/2260 210125/2261 210125/2262 210125/2263 210125/2264 210125/2265 210125/2266 210125/2267 210125/2268 210125/2269 210125/2270 210125/2271 210125/2272 210125/2273

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 we have been notified that a modular LinkSymphoKnee TiNbN Tibial Component was delivered with two uncoated security screws, which is incorrect.
Two screws with TiNbN coating would be correct.

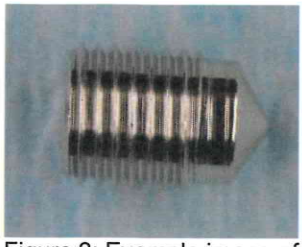

Figure 2: Example image of an incorrect uncoated security screw

2.2 Hazard giving rise to the FSCA*:

If an uncoated screw is implanted, in the worst case there is a risk of irritation of the surrounding soft tissue due to a minimally increased release of ions from the implant materials.

2.3 Probability of problem arising:

The probability of consequences for the patient is to be classified as remote according to the assessments of specialists due to the small surface area of the affected screws (less than 0.5% of the overall surface area).

2.4 Predicted risk to patient/users:

See 2.2 and 2.3

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

Waldemar Link received one complaint regarding a LinkSymphoKnee TiNbN Tibial Component, which was delivered with uncoated security screws. The uncoated screws have the same dimensions as the TiNbN coated screws.

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 products 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 **15.08.2025** 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?:

15.08.2025 – Return of customer reply form
12.09.2025 – Return of products should be completed

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

☐ Yes, the following:	☒ No, because: Regular patient follow-up is sufficient. No additional follow-up is required, as no consequences are to be expected.

3.4 Is customer Reply Required?*:

☒ Yes, until: **15.08.2025**	☐ 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?

15.08.2025 – Return of customer reply form
12.09.2025 – Return of products should be completed
19.09.2025 – Review of customer reply forms & product returns
30.09.2025 – Planned completion of FSCA

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: N/A
Date of previous FSN: N/A

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:

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.