FSN Ref.: R-2023-01
28.02.2023

URGENT FIELD SAFETY NOTICE – New Warnings in the Surgical Technique

Device Commercial Name:

LINK SLED Prosthesis – Femoral Components

CoCrMo Design

CoCrMo/TiNbN Design

LINK SLED Prosthesis - Tibial Plateaus

Metal-backed Design, CoCrMo

Metal-backed Design, CoCrMo/TiNbN

All-poly Design, UHMWPE

For Attention of*:

☒ Distributor / Local branch of manufacturer
☒ Hospital

Contact details of local representative*:

Responsible Person
Dr. Poroshat Khalilpour
Waldemar Link GmbH & Co. KG
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*:

LINK SLED Prosthesis

1.2 Commercial name:

LINK SLED Prosthesis - Femoral Components
LINK SLED Prosthesis - Tibial Plateaus

1.3 Unique Device Identifier (EU UDI-DI):

Article Number	Component / Variant	UDI-DI
15-2020/40	Femoral component, CoCrMo, cemeneted	04026575043897
15-2020/46		04026575209491
15-2020/52		04026575043903
15-2020/60		04026575043910
15-2220/40	Femoral component, CoCrMo cemented, TiNbN coating	04026575429073
15-2220/46		04026575429080
15-2220/52		04026575429097
15-2220/60		04026575429103
15-2028/01	All Poly Tibial component, UHMWPE, CoCrNiMoFe, cemented	04026575043934
15-2028/02		04026575043941
15-2028/03		04026575043958
15-2028/04		04026575043965
15-2028/05		04026575043972
15-2028/06		04026575043989
15-2028/07		04026575043996
15-2028/08		04026575044009
15-2028/09		04026575044016
15-2028/10		04026575044023
15-2028/11		04026575044030
15-2028/12		04026575044047
15-2028/13		04026575359455
15-2028/14		04026575359462
15-2028/15		04026575359479
15-2028/16		04026575359486
15-2030/02	Tibial component, UHMWPE, CoCrMo, cemented, metal backed	04026575044061
15-2030/03		04026575044078
15-2030/04		04026575044085
15-2030/06		04026575044108
15-2030/07		04026575044115
15-2030/08		04026575044122
15-2030/10		04026575044146
15-2030/11		04026575044153
15-2030/12		04026575044160
15-2030/13		04026575436705
15-2030/14		04026575436712
15-2030/15		04026575436729
15-2230/02	Tibial component, UHMWPE, CoCrMo, cemented, TiNbN coating, metal backed	04026575429127
15-2230/03		04026575429134
15-2230/04		04026575429141
15-2230/06		04026575429165
15-2230/07		04026575429172
15-2230/08		04026575429189
15-2230/10		04026575429202
15-2230/11		04026575429219
15-2230/12		04026575429226
15-2230/13		04026575436736
15-2230/14		04026575436743
15-2230/15		04026575436750

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable LINK SLED Prosthesis manufactured by Waldemar Link GmbH & Co. KG is intended for long-term replacement of the femoral and tibial side of a diseased and / or defective knee joint in the human body. The LINK SLED Prosthesis forms a partial replacement of the knee joint. The LINK SLED Prosthesis can be used with full-grown, anesthetized patients of any ethnic origin and sex. The LINK SLED Prosthesis is implanted with 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 orthopedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.

1.5 Article number(s)*:

See 1.3

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

All

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

During current post market surveillance activities, in particular reviews of national endoprosthesis registries, insufficient performance data was observed with regards to the LINK SLED prosthesis.
Aseptic loosening and increased wear of the tibial plateau were the main issues addressed in the registry data.
As part of the risk analysis and further investigations which we carried out together with product specialists and medical consultants, it was found that for safe and reliable use of the implants, the surgical technique must be expanded at specific sequences and the importance of individual passages must be clearly marked.
Appropriate knowledge of the application of the LINK Sled Prosthesis must be ensured through user training.
In this matter, two new WARNINGs have been added to the adapted surgical technique, which the Waldemar Link GmbH & Co. KG would like to publish with this Field Safety Notice.

2.2 Hazard giving rise to the FSCA*:

Hazards for the patient could be early aseptic loosening or increased wear of the implant caused by suboptimal positioning of the implant or inadequate cementing technique leading to an unsatisfactory surgical result, and in the worst case, intervention or revision earlier than expected.

2.3 Probability of problem arising:

A higher likelihood of occurrence was classified by our risk analyses.

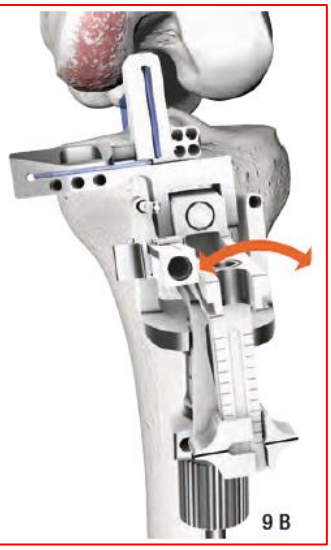
2.4 Predicted risk to patient/users:

A malpositioned tibial plateau could possibly lead to a changed load application of the product and may result in aseptic loosening or increased wear of the tibial plateau. Inadequate cementing technique can lead to premature failure of the joint reconstruction

2.5 Further information to help characterize the problem:

WARNING - see also Page 13 of attached surgical technique

Varus-valgus Adjustment (B)
Precise varus or valgus alignment is possible with fine adjustment.
Warning: Overcorrection in valgus should be avoided under all circumstances. Position the tibia in 0° to 3° varus. Place the Alignment Rod through the Tibial Cutting Block Assembly to check position of the cut plane to avoid overcorrection.



WARNING - see also Page 22 of attached surgical technique

Implantation and Cementation

Warning:
A good fixation of the implant components is a prerequisite to achieve long-term success of the application. Cementing technique is one of the factors that play an important role in this respect. Therefor the following instructions have to be carefully considered.

2.6 Background on Issue:

N/A

2.7 Other information relevant to FSCA:

Following the Field Safety Notice, Waldemar Link GmbH & Co. KG will offer an **intensive user training program during 2023** regarding the LINK SLED Prosthesis.
Users in Germany will be trained directly by LINK.
The product training of the users in international markets is ensured by foreign branches or by local distributors after instruction by LINK employees.
Participation is required for further use of the product.

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 the Surgical Technique**
☐ Other
☐ None

3.2 By when should the action be completed ?:

Please reply to us in any event until the **15.03.2023** as documentation of the FSN. This applies even if you have currently none of the listed products in stock.

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

We recommend continuing with the regular follow-up.

3.4 Is customer Reply Required ?* :

☒ Yes, until: **15 March 2023** ☐ No

3.5 Action being taken by the manufacturer

☐ Product Removal
☐ On-site device modification / inspection
☐ Software upgrade
☒ **Change of IFU and Surgical Technique**
☒ **Other: User Training**
☐ None

3.6 By when should the action be completed ?

User Trainings are planned to be performed during 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: 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 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:

Distributor Reply Form
Surgical Technique - LINK SLED prosthesis (English)

4.10 Name/Signature:

Dr. Poroshat 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.