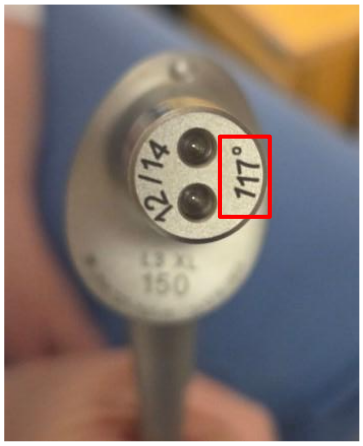
FSN Ref.: R-2026-03 #02
23.03.2026

URGENT FIELD SAFETY NOTICE – Product Recall

Device Commercial Name:

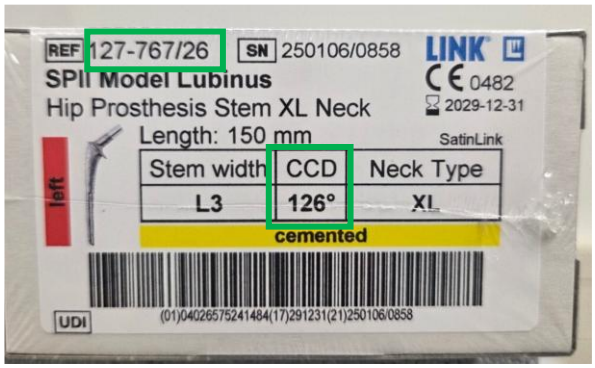
SPII Model Lubinus, Hip Prosthesis Stem XL Neck, cemented, L= 150 mm, left L3, large, CCD 126°, CoCrMo, anatomical, Taper 12/14 [Article Ref 127-767/26]



Incorrect
CCD-Angle: 117°
Article Ref: 127-767/17

Correct
CCD-Angle: 126°
Article Ref: 127-767/26

Figure 1: The device laser markings of the affected SPII Hip Stem 127-767/26 show the incorrect Article Ref and CCD-Angle.



All information on the labels are correct

CCD-Angle: 126°
Article Ref: 127-767/26

Figure 2: The labels of the affected SPII Hip Stem 127-767/26 show the correct Article Ref and CCD-Angle.

For Attention of*:

- ☒ Distributor / Local branch of manufacturer
- ☒ Hospital

Contact details of local representative*:

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*:

SPII Model Lubinus, Hip Prosthesis Stem

1.2 Commercial name:

Hip Prosthesis Stem XL Neck, cemented, L= 150 mm, left L3, large, CCD 126°, CoCrMo, anatomical, Taper 12/14

1.3 Unique Device Identifier (EU UDI-DI):

04026575241484

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable SPII Model Lubinus Hip Stems manufactured by Waldemar Link GmbH & Co. KG are intended for long-term replacement of the femoral side of a diseased and / or defective hip joint in the human body. The SPII Model Lubinus Hip Stems form a hemiarthroplasty of the hip joint when combined with trauma heads (e.g. modular trauma heads or large heads) and form a total replacement of the hip joint if combined with prosthesis heads and an acetabular cup. The SPII Model Lubinus Hip Stems can be used with full-grown, anesthetized patients of any ethnic origin and sex. The SPII Model Lubinus Hip Stems are 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)*:

127-767/26

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

Article Ref 127-767/26			
ID-Number	ID-Number	ID-Number	ID-Number
241218/2821	241218/2831	250106/0848	250106/0858
241218/2822	241218/2832	250106/0849	250106/0859
241218/2823	241218/2833	250106/0850	250106/0860
241218/2824	250106/0841	250106/0851	250106/0861
241218/2825	250106/0842	250106/0852	250106/0862
241218/2826	250106/0843	250106/0853	250106/0863
241218/2827	250106/0844	250106/0854	250106/0864
241218/2828	250106/0845	250106/0855	250106/0865
241218/2829	250106/0846	250106/0856	250106/0866
241218/2830	250106/0847	250106/0857	250106/0867

The expiry date for the affected articles is 31.12.2029.

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 the device laser markings of one production order of SPII Model Lubinus Hip Stems with the article Ref 127-767/26 show the incorrect Article Ref 127-767/17 and the wrong CCD-Angle 117°.

2.2 Hazard giving rise to the FSCA*:

The wrong device markings may lead to confusion during the surgery. In the worst case, this could lead to a modified or prolonged surgery.

2.3 Probability of problem arising:

It is assumed that all the listed serial numbers of one production order (see point 1.7) have incorrect device laser markings. The probability that the occurrence of the error results in a prolonged or modified surgery is remote.

2.4 Predicted risk to patient/users:

Please refer to 2.2. There is no risk for patients who have already been treated because the item dimensions match the main label and patient label.

2.5 Further information to help characterize the problem:

The information on the main label and patient label is correct. The incorrect laser marking is visible on the item and could be detected during surgery prior implantation.

2.6 Background on Issue:

A 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 **06.04.2026** 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?:

The deadlines were updated due to the follow-up FSN.
Return the reply form: 06.04.2026
Return of the products: 30.04.2026

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

☐ Yes, the following:	☒ No, because: There is no risk for patients who have already been treated because the item dimensions match the main label and patient label. There is no impact on future surgeries.

3.4 Is customer Reply Required?*:

☒ Yes, until: **06.04.2026**	☐ 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?

Return of the products: **23.04.2026**
Expected completion of the recall: **07.05.2026**

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

☐ Yes	☒ No, see 3.3	☐ 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: Additional affected customers were identified.

4.2 For updated FSN

Reference number of previous FSN: R-2026-03
Date of previous FSN: 06.02.2026

4.3 For updated FSN, key new information as follows:

An internal investigation identified two additional customers that are affected. The deadlines for the customer reply and the return of the products were adjusted due to the follow-up FSN.

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:

Poroshat Khalilpour

Digital unterschrieben von Poroshat Khalilpour
Datum: 2026.03.23 10:03:36 +01'00'

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.