

URGENT FIELD SAFETY NOTICE – Product Recall

Device Commercial Name:

LINK Prosthesis Head B, Ø 28 mm, Neck L= L+, + 7 mm, Taper 12/14, CoCrMo


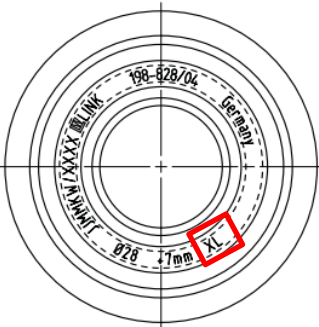



Figure 1: Exemplary illustration of Prosthesis Heads B



Incorrect:
Neck Length: XL

Correct:
Neck Length: L+

Figure 2: Example illustration of the error in the direct part marking. The direct part marking on the affected Prosthesis Heads B shows the incorrect neck length.



All information on the labels is correct.
Neck Length: L+

Head-Ø mm	Neck Length	Neck Length mm
28	L+	+7

Figure 3: The labels on the affected Prosthesis Heads B show the correct neck length.

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*:

LINK Prosthesis Head B

1.2 Commercial name:

Prosthesis Head B, Ø 28 mm, Neck L= L+, + 7 mm, Taper 12/14, CoCrMo

1.3 Unique Device Identifier (EU UDI-DI):

04026575193783

1.4 Primary clinical purpose of device*:

The Prosthesis Heads B are part of a mechanical reconstruction of the hip joint. The Prosthesis Heads B for total and hemi hip arthroplasty are small metal balls that are placed onto the hip stem. Due to the conical design of the 12/14 taper the head sits firmly on the stem and requires no additional fixation. The non-active, surgically-invasive implantable Prosthesis Head B manufactured by Waldemar Link GmbH & Co. KG is intended to be used as part of a long-term replacement of a diseased and / or defective hip joint in the human body. The Prosthesis Head B forms a replacement of the hip joint when combined with the prosthesis stem and the acetabular cup or the bipolar head. The Prosthesis Head B can be used with full-grown, anesthetized patients of any ethnic origin and sex. 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 orthopedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.

1.5 Article number(s)*:

198-828/04

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

Article number 198-828/04			
ID-Number:	ID-Number:	ID-Number:	ID-Number:
200526/0006	220204/0620	231207/0147	231207/0188
200526/0008	220204/0627	231207/0150	240415/3854
200526/0029	220304/0074	231207/0153	240415/3865
210302/0071	220304/0075	231207/0157	240415/3872
210910/0003	221011/0078	231207/0164	
220204/0615	221011/0099	231207/0167	
220204/0616	231207/0144	231207/0180	

Manufacture dates: December 1, 2025 to January 1, 2026
Expiry dates: November 30, 2030 to December 31, 2030

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

Internally, it was noticed that the direct part marking of two production orders for Prosthesis Heads B shows the wrong neck length. Instead of “L+”, the prosthesis head is marked with “XL”. The information on the main label and the patient label is correct.

2.2 Hazard giving rise to the FSCA*:

The wrong direct part marking 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 the affected production orders (see point 1.7) have incorrect direct part marking.

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 direct part marking is visible on the item and could be detected during surgery prior implantation.

2.6 Background on Issue:

To date, Waldemar Link has not received any complaints regarding this article and the circumstances described.

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 **04.03.2026** 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?:

04.03.2026 - Return of the customer / distributor reply form
03.04.2026 - Product return 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:

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: 04.03.2026

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?

10.04.2026 - Review of customer / distributor response forms and product returns 21.04.2026 - Expected completion of the recall
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3.7 Is the FSN required to be communicated to the patient /lay user?

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
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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?

<input type="checkbox"/> appended to this FSN <input type="checkbox"/> not appended to this FSN
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4. General Information

4.1 FSN Type*:

<input checked="" type="checkbox"/> New	<input type="checkbox"/> Update
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4.2 For updated FSN

Reference number of previous FSN: N/A Date of previous FSN: N/A
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4.3 For updated FSN, key new information as follows:

N/A

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

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not planned yet
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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*:

<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
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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.

FSN Ref.: R-2026-05
18.02.2026

Field Safety Notice
Customer Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2026-05
FSN Date*	18.02.2026
Product / Device name*	Prosthesis Head B, Ø 28 mm, Neck L= L+, + 7 mm, Taper 12/14, CoCrMo
Article Number(s)	198-828/04
Batch(es) / Serial Number(s)	200526/0006 200526/0008 200526/0029 210302/0071 210910/0003 220204/0615 220204/0616 220204/0620 220204/0627 220304/0074 220304/0075 221011/0078 221011/0099 231207/0144 231207/0147 231207/0150 231207/0153 231207/0157 231207/0164 231207/0167 231207/0180 231207/0188 240415/3854 240415/3865 240415/3872 Manufacture dates: December 1, 2025 to January 1, 2026 Expiry dates: November 30, 2030 to December 31, 2030

2. Customer Details

Account Number	
Healthcare Organisation Name*	
Address*	
Department / Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation

<input type="checkbox"/> I confirm receipt of the Field Safety Notice and that I read and understood its content.	Tick all that apply or enter N/A:		
<input type="checkbox"/> I performed all actions requested by the FSN.	Tick all that apply or enter N/A:		
<input type="checkbox"/> The information and required actions have been brought to the attention of all relevant users and executed.	Tick all that apply or enter N/A:		
<input type="checkbox"/> I have returned affected devices. [Enter number of devices returned and date]	Qty:	Batch(es) / Serial Number(s)	Date returned:
	N/A:	Comments:	
<input type="checkbox"/> Affected devices are not available for return (e.g. implanted). [Enter number of devices implanted and date]	Qty:	Batch(es) / Serial Number(s)	Date implanted:
	N/A:	Comments:	
Name*	Customer print name here:		
Signature*			
Date*			

4. Return acknowledgement to sender

Email	complaint@link-ortho.com
Customer Helpline	<p>Questions about the products or return of the products: Please contact your Export Manager</p> <p>Questions about customer information: Complaint & Vigilance Management complaint@link-ortho.com +49 40 5 39 95 - 482</p>
Postal Address	WALDEMAR LINK GmbH & Co. KG Barkhausenweg 10 22339 Hamburg Deutschland
Web Portal	https://www.link-ortho.com/
Fax	+49 40 539 95 – 174
Deadline for returning the customer reply form*	02.03.2026

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

FSN Ref.: R-2026-05

18.02.2026

Field Safety Notice Distributor Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2026-05
FSN Date*	18.02.2026
Product / Device name*	Prosthesis Head B, Ø 28 mm, Neck L= L+, + 7 mm, Taper 12/14, CoCrMo
Article Number(s)	198-828/04
Serial Number(s)	200526/0006 200526/0008 200526/0029 210302/0071 210910/0003 220204/0615 220204/0616 220204/0620 220204/0627 220304/0074 220304/0075 221011/0078 221011/0099 231207/0144 231207/0147 231207/0150 231207/0153 231207/0157 231207/0164 231207/0167 231207/0180 231207/0188 240415/3854 240415/3865 240415/3872 Manufacture dates: December 1, 2025 to January 1, 2026 Expiry dates: November 30, 2030 to December 31, 2030

2. Distributor / Importer Details

Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Measures taken by the Distributor / Importer

<input type="checkbox"/> I confirm receipt of the Field Safety Notice and that I read and understood its content.	Tick all that apply or enter N/A:		
<input type="checkbox"/> I have checked my stock and quarantined inventory.	Distributor / Importer to enter quantity and date:		
<input type="checkbox"/> I have identified customers that received or may have received this device.	Tick all that apply or enter N/A:		
<input type="checkbox"/> I have attached customer list.	Tick all that apply or enter N/A:		
<input type="checkbox"/> I have informed the identified customers of this FSN.	Date of communication:		
<input type="checkbox"/> I have received confirmation of reply from all identified customers.	Tick all that apply or enter N/A:		
<input type="checkbox"/> I have returned affected devices. [Enter number of devices returned and date]	Qty:	Batch(es) / Serial Number(s)	Date returned:
	N/A:	Comments:	
<input type="checkbox"/> Affected devices are not available for return (e.g. implanted). [Enter number of devices implanted and date]	Qty:	Batch(es) / Serial Number(s)	Date implanted:
	N/A:	Comments:	
Print Name*	Customer print name here:		
Signature*			
Date*			

4. Return acknowledgement to sender

Email	complaint@link-ortho.com
Customer Helpline	Questions about the products or return of the products: Please contact your Export Manager Questions about customer information: Complaint & Vigilance Management complaint@link-ortho.com +49 40 5 39 95 - 482
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