

**URGENT FIELD SAFETY NOTICE – Product Recall**

Device Commercial Name:

Endo-Model M - Instrument  
Femoral Trial, right, S, Stainless Steel



Figure 1: Femoral Trial, right with correct side marking



Figure 2: Femoral Trial, right with incorrect side marking

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](mailto: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\*:**

Endo-Model M - Instrument

**1.2 Commercial name:**

Femoral Trial, right, S, Stainless Steel

**1.3 Unique Device Identifier (EU UDI-DI):**

04026575363964

**1.4 Primary clinical purpose of device\*:**

The non-active, surgically invasive implantable Endo Model Knee System 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 Endo Model Knee System forms a total replacement of the knee joint.

The femoral trial is used for trial repositioning to ensure the correct position and size of the selected femoral implant.

**1.5 Article number(s)\*:**

15-3234/07

**1.6 Software version:**

N/A

**1.7 Affected serial or lot number range:**

LOT C534017 and C545057

**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, Waldemar Link was informed that the direct part marking of two batches of right femoral trial components show the incorrect - "L" for left instead of "R" for right.

### 2.2 Hazard giving rise to the FSCA\*:

The wrong direct part marking may lead to a prolonged surgical procedure should the mislabeling only be identified intraoperatively.

### 2.3 Probability of problem arising:

The probability of a prolonged surgical procedure is considered probable if an incorrectly marked femoral trial is used during the surgical procedure.

### 2.4 Predicted risk to patient/users:

Please refer to 2.2.

### 2.5 Further information to help characterize the problem:

The error can be identified at an early stage through label comparison or during instrument tray assembly.

### 2.6 Background on Issue:

N/A

### 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\*:

<p><input checked="" type="checkbox"/> Identify Device</p> <p><input checked="" type="checkbox"/> Quarantine Device</p> <p><input checked="" type="checkbox"/> Return Device</p> <p><input type="checkbox"/> Destroy Device</p> <p><input type="checkbox"/> On-site device modification / inspection</p> <p><input type="checkbox"/> Follow patient management recommendations</p> <p><input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU)</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> None</p> <ul style="list-style-type: none"><li>• Should you have any of the affected products in your inventory, please send the products back to Waldemar Link GmbH &amp; Co. KG.</li><li>• Replacement will not incur any costs to you. Should you have any questions on acquiring replacements for forthcoming surgeries, please contact your local sales representative or customer service for Link products.</li><li>• Please return the reply form to us in any event until the <b>27.02.2026</b> 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.</li></ul>
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#### 3.2 By when should the action be completed?:

27.02.2026 – Deadline for returning FSN customer reply forms
27.02.2026 – Review of returned instruments and customer reminders

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

<input type="checkbox"/> Yes, the following:	<input checked="" type="checkbox"/> No, because: It is a femoral trial (instrument).
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#### 3.4 Is customer Reply Required?\*

<input checked="" type="checkbox"/> Yes, until: 27.02.2026	<input type="checkbox"/> No
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#### 3.5 Action being taken by the manufacturer:

<p><input checked="" type="checkbox"/> Product Removal</p> <p><input type="checkbox"/> On-site device modification / inspection</p> <p><input type="checkbox"/> Software upgrade</p> <p><input type="checkbox"/> IFU or labelling change</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> None</p>
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**3.6 By when should the action be completed?**

27.02.2026 – Deadline for returning FSN customer reply forms 27.02.2026 – Review of returned instruments and customer reminders 31.03.2026 – Planned closure of the FSCA
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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 checked="" type="checkbox"/> not appended to this FSN
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#### 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.

**FSN Ref.: R-2026-04**  
**13.02.2026**

**Field Safety Notice**  
**Customer Reply Form**

**1. Field Safety Notice information**

FSN Reference number*	R-2026-04
FSN Date*	13.02.2026
Product / Device name*	Femoral Trial, right, S, Stainless Steel
Article Number(s)	15-3234/07
Batch(es)	C534017, manufactured 01.10.2025 C545057, manufactured 04.01.2025

**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)	Date returned:
	N/A:	Comments:	
<input type="checkbox"/> Affected devices are not available for return (e.g. destroyed). [Enter number of devices implanted and date]	Qty:	Batch(es)	Date destroyed:
	N/A:	Comments:	
<input type="checkbox"/> Other Action (Define):	Tick all that apply or enter N/A:		
Name*	Customer print name here:		
Signature*			
Date*			

### 4. Return acknowledgement to sender

Email	<b>complaint@link-ortho.com</b>
Customer Helpline	<b>Questions about the products or return of the products:</b> Please contact your Export Manager  <b>Questions about customer information:</b> Complaint & Vigilance Management complaint@link-ortho.com +49 40 5 39 95 - 784
Postal Address	WALDEMAR LINK GmbH & Co. KG Barkhausenweg 10 22339 Hamburg Deutschland
Web Portal	<a href="https://www.link-ortho.com/">https://www.link-ortho.com/</a>
Fax	<b>+49 40 539 95 – 174</b>
Deadline for returning the customer reply form*	<b>27.02.2026</b>

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.