FSN Ref.: R-2025-06
08.08.2025

URGENT FIELD SAFETY NOTICE – Product Recall

Device Commercial Name:

Endo-Model -M Modular Knee Prosthesis System, Tibial Component, cemented
Endo-Model -M Modular Knee Prosthesis System, Modular Joint Component Unit, cemented

Figure 1: Example image Endo-Model M Tibial Component and Modular Joint Unit

GEMINI SL Total Knee System, Tibial Component, Mobile Bearing, SMS, uncemented

Figure 2: Example image Gemini SL Tibial Component

CustomLINK Joint component Uni Endo-Model-M
CustomLINK Connection Component Endo-Modell SL

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*:

Endo-Model - M Modular Knee Prosthesis System
GEMINI SL Total Knee System
CustomLINK knee prosthesis

1.2 Commercial name:

1. Endo-Model -M Modular Knee Prosthesis System, Tibial Component, cemented, UHMWPE, CoCrMo, Ti6Al4V, M, Rotating Hinge
2. Endo-Model -M Modular Knee Prosthesis System, Modular Joint Component Unit, cemented, UHMWPE, CoCrMo, Ti6Al4V, right, Width= 55 mm, XS, Rotating Hinge
3. GEMINI SL Total Knee System, Tibial Component, Mobile Bearing, SMS, uncemented, right, Sz. medium, R3, CoCrMo/TiCaP
4. CustomLINK Joint component unit Endo-Model-M, rotational version, distal femoral replacement, 8° hyperextension, right, large, cemented
5. CustomLINK Connection component with interlocking for knee prosthesis Endo-Model SL, small

1.3 Unique Device Identifier (EU UDI-DI):

1. 04026575316298
2. 04026575316007
3. 04026575344819
4. N/A
5. N/A

1.4 Primary clinical purpose of device*:

The **Endo-Model - M** Prosthesis is a modular knee surface replacement component. It comes in an anatomical design and is available in right and left version. Further, it offers a 6° valgus angle on the femoral side. It is available in for different sizes: XS, S, M and L. There is no cross-over sizing possible.
The Endo-Model - M includes 48 components including a Rotating Hinge (8 Joint Units, 8 Femurs, 4 tibias and 8 Joint Units in PorEx) and a Pure Hinge (8 Joint Units, 8 Femurs and 4 tibias). The Endo-Model -M comes as a Joint Unit or Femur and Tibia in a separate package.

The **GEMINI SL** Total Knee System is a mechanical reconstruction of the knee joint. The GEMINI SL Total Knee System is a bicondylar joint prosthesis which is available in different configurations allowing either posterior cruciate ligament retaining (CR) or posterior cruciate ligament sacrificing (CS) or posterior cruciate substituting (PS) procedure. The GEMINI SL Total Knee System consists of femoral components, articular surfaces, tibial components including tibia stems and patella resurfacing components.
It comes in different sizes for femur and tibia and different heights for the articular surfaces. There are 8 sizes left and 8 sizes right for femoral replacement and 5 sizes each left and right for the tibial replacement. There are 4 heights for the articular surface Mobile Bearing and 5 heights for the articular surface Fixed Bearing (CR and PS). For the femoral and the tibial components there is a version for cemented application and a version for cementless application available.

CustomLINK prostheses are custom-made and explicitly manufactured for the patient documented under an individual case number and his or her individual defect and anatomy situation and is specially adapted to the indication described by the treating physician.

1.5 Article number(s)*:

1. 15-2814/03 - Endo-Model M
2. 15-2815/11 - Endo-Model M
3. 318-316/03 - Gemini SL
4. 11C009405313-08644 - CustomLINK
5. 11C009635313-05834 - CustomLINK

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

Article number	Serial number	Product system
15-2814/03	250308/2888	Endo-Model M
15-2814/03	250308/2886	Endo-Model M
15-2814/03	250308/2887	Endo-Model M
15-2814/03	250324/1798	Endo-Model M
15-2815/11	240109/1094	Endo-Model M
15-2815/11	240109/1095	Endo-Model M
15-2815/11	240109/1096	Endo-Model M
15-2815/11	240710/0379	Endo-Model M
15-2815/11	240710/0406	Endo-Model M
15-2815/11	240710/0407	Endo-Model M
15-2815/11	240710/0408	Endo-Model M
15-2815/11	240710/0409	Endo-Model M
15-2815/11	240710/0410	Endo-Model M
15-2815/11	240710/0378	Endo-Model M
15-2815/11	240710/0380	Endo-Model M
318-316/03	201013/0082	Gemini SL
318-316/03	201013/0084	Gemini SL
318-316/03	201013/0089	Gemini SL
318-316/03	201013/0090	Gemini SL
11C009405313-08644	240702/0189	CustomLINK
11C009635313-05834	210528/0117	CustomLINK

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

It has been identified that the supplied material of the CoCr round bars with batch number 2447069 does not comply with the material specification requirements. The elongation at break does not comply with the MSpec and the requirements of the standard and the material may behave differently under load than specified.

This material is used for subcomponents such as grub screws / stem security screws and plateau anchoring screws / articulating surface fixation screws in knee prostheses. The implants listed under 1.7 contain affected subcomponents.

2.2 Hazard giving rise to the FSCA*:

If an affected knee prosthesis is implanted, there is a risk that the affected subcomponent may fail prematurely, which could impair the application of the prosthesis.

2.3 Probability of problem arising:

According to expert assessments, the probability of consequences for the patient is classified as occasional.

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:

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*:

☒ Identify Device
☒ Quarantine Device
☒ Return Device
☐ Destroy Device
☒ On-site device modification (only for custom-made products / CustomLINK)
☐ 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 **22.08.2025** 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.
- **EXCEPTION**:
  Replacement screws will be delivered for 2 custom-made CustomLINK products.

3.2 By when should the action be completed?:

22.08.2025 – Return of customer reply form
29.08.2025 – 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.

3.4 Is customer Reply Required?*:

☒ Yes, until: **22.08.2025**	☐ No

3.5 Action being taken by the manufacturer:

☒ Product Removal
☒ On-site device modification (only for custom-made products / CustomLINK)
☐ Software upgrade
☐ IFU or labelling change
☐ Other
☐ None

3.6 By when should the action be completed?

22.08.2025 – Return of customer reply form 29.08.2025 – Return of products should be completed 12.09.2025 – 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.

FSN Ref.: R-2025-06
08.08.2025

Field Safety Notice
Distributor / Importer Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2025-06
FSN Date*	08.08.2025

Artikelnummer	Seriennummer	Produktsystem
15-2814/03	250308/2888	Endo-Model M
15-2814/03	250308/2886	Endo-Model M
15-2814/03	250308/2887	Endo-Model M
15-2814/03	250324/1798	Endo-Model M
15-2815/11	240109/1094	Endo-Model M
15-2815/11	240109/1095	Endo-Model M
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15-2815/11	240710/0409	Endo-Model M
15-2815/11	240710/0410	Endo-Model M
15-2815/11	240710/0378	Endo-Model M
15-2815/11	240710/0380	Endo-Model M
318-316/03	201013/0082	Gemini SL
318-316/03	201013/0084	Gemini SL
318-316/03	201013/0089	Gemini SL
318-316/03	201013/0090	Gemini SL
11C009405313-08644	240702/0189	CustomLINK
11C009635313-05834	210528/0117	CustomLINK

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

☐ I confirm receipt of the Field Safety Notice and that I read and understood its content.	Tick all that apply or enter N/A:		
☐ I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date:		
☐ I have identified customers that received or may have received this device			
☐ I have attached customer list			
☐ I have informed the identified customers of this FSN	Date of communication:		
☐ I have received confirmation of reply from all identified customers			
☐ I have returned affected devices [Enter number of devices returned and date complete]	Qty:	Lot/Serial Number(s):	Date Returned:
	N/A:	Comments:	
☐ Affected devices are not available for return because they are implanted [Enter number implanted and date]	Qty:	Serial Number(s):	Date Implanted:
	N/A:	Comments:	
☐ Affected devices are not available for return because they have been discarded [Enter number discarded and date]	Qty:	Lot/Serial Number(s):	Date Discarded:
	N/A:	Comments:	
☐ The affected device is a CustomLINK device. The surgery will be performed with provided replacement screws.			
Print Name*	Distributor/Importer print name here:		
Signature*	Distributor/Importer sign Here:		
Date*			

4. Return acknowledgement to sender

Email	complaint@link-ortho.com
Customer Helpline	**Questions about the products:** Please contact your Export Manager **Questions about recall:** Complaint Management complaint@link-ortho.com +49 40 5 39 95 – 432
Postal Address	WALDEMAR LINK GmbH & Co. KG Barkhausenweg 10 22339 Hamburg Germany
Web Portal	https://www.link-ortho.com/
Fax	**+49 40 539 95 – 174**
Deadline for returning the Distributor / Importer reply form*	22.08.2025

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.