FSN Ref.: R-2024-04
30.04.2024

URGENT FIELD SAFETY NOTICE – Product Recall

Device Commercial Name:

Femoral Component, Condylar Replacement, right and left, XS

Article REF: 15-8542/02; 15-8542/04

LINK Endo-Model EVO -W

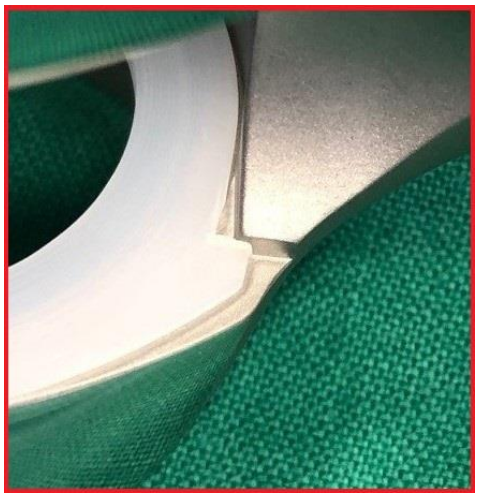

Figure 1: Affected interface - UHMWPE bearing shell and Femoral Component.
Figure 2: A closer view of the interface with the mechanical stop and the bearing shell.

For Attention of*:

☒ Distributor / Local branch of manufacturer
☒ Hospital

Contact details of local representative* [Deputy]**:**

Annerike-Tizia Hucklenbroch
Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany
E-Mail: vigilance@link-ortho.com
Tel. +49 (0)40 5 39 95 432

Risk addressed by FSN

1. Information on Affected Device

1.1 Device Type*:

Endo-Model Knee System / LINK Endo-Model EVO Knee System

1.2 Commercial name:

LINK Endo-Model EVO -W, Modular Joint Component, Femoral Component, uncemented, Condylar Replacement, right, XS, UHMWPE, CoCrMo, Rotating Hinge, Width= 55 mm
LINK Endo-Model EVO -W, Modular Joint Component, Femoral Component, uncemented, Condylar Replacement, left, XS, UHMWPE, CoCrMo, Rotating Hinge, Width= 55 mm

1.3 Unique Device Identifier (EU UDI-DI):

Article REF	UDI-DI
15-8542/02	04026575182589
15-8542/04	04026575182596

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable Endo-Model Knee System, LINK Endo-Model EVO Knee System (including Link OptiStem) 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, LINK Endo-Model EVO Knee System (including Link OptiStem) forms a total replacement of the knee joint. The Endo-Model Knee System, LINK Endo-Model EVO Knee System (including Link OptiStem) can be used with full-grown, anesthetized patients of any ethnic origin and sex. The Endo-Model Knee System, LINK Endo-Model EVO Knee System (including Link OptiStem) is implanted with or without cement related to the selected implant version. 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.
This Femoral Component is to replace the distal femoral bone.

1.5 Article number(s)*:

15-8542/02; 15-8542/04

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

15-8542/02			15-8542/04	
190415/0013	190415/0026	190415/0038	191028/3230	191028/3237
190415/0014	190415/0027	190415/0039	191028/3231	191028/3240
190415/0016	190415/0028	200120/3756	191028/3232	191028/3241
190415/0017	190415/0029	200120/3757	191028/3233	191028/3242
190415/0018	190415/0030	200120/3758	191028/3234	191028/3243
190415/0019	190415/0031		191028/3235	191028/3244
190415/0020	190415/0032		191028/3236	191028/3245

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

Internally, it has been noticed that the design of the borehole of the distal Femoral Component does not match the design of the bearing shell. At the mechanical stop shown in the picture, there is no sufficient contact surface at the interface. As a result, the bearing shell may not be sufficiently secured against stronger rotational forces.
Only size XS is affected.

2.2 Hazard giving rise to the FSCA*:

A possible hazard could be a reduced standing time due to rotating or jamming of the bearing shell. This would be noticeable through stiffness or instability in the knee joint.

2.3 Probability of problem arising:

The probability of the bearing shell rotating or jamming is assumed to be remote, as it depends on the rotational forces acting on the knee joint.

2.4 Predicted risk to patient/users:

It is assumed that the knee joint prosthesis is functional, after correct implantation. If stiffness or instability develops in the knee joint, please contact your doctor immediately for a follow-up check. If there is an indication for a replacement operation of the bearing shells, the connection mechanism or the polyethylene components, we can offer you a custom-made replacement set adapted to the design. This can be produced on request.
Preventive surgery without a corresponding indication is not necessary.

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 / inspection
☒ Follow patient management recommendations, if implanted
☐ Take note of amendment / reinforcement of Instructions For Use (IFU)
☒ Other: Custom-made replacement set can be requested
☐ None

Should you have any of the affected product in your inventory, please send the products back to Waldemar Link GmbH & Co. KG.

- 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 **15.05.2024** as documentation of the recall. This applies even if you have none of the listed products in stock.

3.2 By when should the action be completed?:

The reply should be completed until 15.05.2024.
If the product has already been implanted, please inform the patient until 15.05.2024.
If the product is available for return, please send it back until 15.05.2024.

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

☒ Yes, the following:

1. It is assumed that the knee joint prosthesis is functional after correct implantation.
2. If stiffness or instability develops in the knee joint, please contact your doctor immediately for a follow-up check.
3. If there is an indication for a replacement surgery of the bearing shells, the connection mechanism or the polyethylene components, we can offer you a custom-made replacement set adapted to the design.
   This can be produced on request.

Preventive surgery without a corresponding indication is not necessary!

3.4 Is customer Reply Required?*:

☒ Yes, until: 15.05.2024 ☐ No

3.5 Action being taken by the manufacturer:

☒ Product Removal
☐ On-site device modification / inspection
☐ Software upgrade
☐ IFU or labelling change
☒ Other: Field safety notice for user and patient
☐ None

3.6 By when should the action be completed?

The reply forms and the returns will be checked by 15.05.2024.
Reminder will be send out to outstanding customers.
The completion will follow as soon as all replies have been received, approximately by 15.06.2024.

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: The information provided in this FSN is considered sufficient

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:

Reply form including status request of affected products.

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.

URGENT FIELD SAFETY NOTICE – Product Recall
Distributor / Importer Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2024-04
FSN Date*	30. April 2024
Product / Device name*	LINK Endo-Model EVO -W, Modular Joint Component, Femoral Component, uncemented, Condylar Replacement, right and left, XS
Product Code	15-8542/02; 15-8542/04
Batch / Serial Number(s)	See FSN (Section 1.7)

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 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 returned affected devices	Qty:	Lot/Serial Number(s):	Date Returned:
☐ Affected devices are not available for return as already implanted. **The information was forwarded to the clinic and patient.**	Qty:	Lot/Serial Number(s):	Date Implanted:

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 replacement & products:** Please contact your Export Manager **Questions about recall:** Complaint Management complaint@link-ortho.com +49 40 5 39 95 - 523
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*	15.05.2024

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.