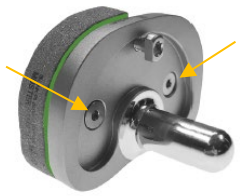
FSN Ref.: R-2024-05
22.05.2024

URGENT FIELD SAFETY NOTICE – Advisory Notice

Device Commercial Name:

Tibial Components / Modular Joint Component Units,
Endo-Model – M Modular Knee Prosthesis System



Tibial Components,
Endo-Model SL Rotational and Hinge Knee Prosthesis System

For Attention of*:

☒ Distributor / Local branch of manufacturer

☒ Hospital

Contact details of local representative*:

Responsible Person
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*:

Tibial Components

1.2 Commercial name:

Tibial Components / Modular Joint Component Units,
Endo-Model– M Modular Knee Prosthesis System

Tibial Components,
Endo-Model SL Rotational and Hinge Knee Prosthesis System

1.3 Unique Device Identifier (EU UDI-DI):

Endo-Model–M				
04026575316243	04026575316076	04026575316595	04026575164028	04026575386420
04026575316281	04026575316083	04026575316601	04026575164035	04026575386437
04026575316298	04026575316731	04026575316618	04026575383207	04026575386444
04026575316304	04026575316748	04026575316625	04026575383221	04026575386451
04026575316007	04026575316755	04026575034727	04026575383238	
04026575316014	04026575316762	04026575034734	04026575383245	
04026575316021	04026575316557	04026575034741	04026575383269	
04026575316038	04026575316564	04026575034758	04026575383283	
04026575316052	04026575316571	04026575164042	04026575386406	
04026575316069	04026575316588	04026575164059	04026575386413	

Endo-Model SL				
04026575359202	04026575370870			
04026575359219	04026575370887			
04026575359226	04026575370894			

1.4 Primary clinical purpose of device*:

This knee joint system is highly modular, and can therefore be employed in difficult primary and revision procedures. For restoring the joint line in tumor and revision cases, special proximal spacers are available to compensate deficits in the flexion and extension gap.

1.5 Article number(s)*:

Endo-Model–M				
15-2814/01	15-2818/11	15-2837/11	15-3818/11	15-8521/29
15-2814/02	15-2818/12	15-2837/12	15-3818/12	15-8521/31
15-2814/03	15-2834/01	15-2838/11	15-8521/05	15-8521/33
15-2814/04	15-2834/02	15-2838/12	15-8521/07	15-8521/35
15-2815/11	15-2834/03	15-3815/11	15-8521/09	
15-2815/12	15-2834/04	15-3815/12	15-8521/11	
15-2816/11	15-2835/11	15-3816/11	15-8521/13	
15-2816/12	15-2835/12	15-3816/12	15-8521/15	
15-2817/11	15-2836/11	15-3817/11	15-8521/25	
15-2817/12	15-2836/12	15-3817/12	15-8521/27	

Endo-Model SL				
16-2817/02	16-2817/32			
16-2817/05	16-2817/35			
16-2817/07	16-2817/37			

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

All after manufacturing date 2022-06 **until** manufacturing date 2024-06

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

There is a risk that the blind screws of the modular tibial component cannot be loosened intraoperatively. This is necessary if an uncemented Tilastan Proximal Tibial Spacer or Proximal Tibial Segment is to be screwed in which is only needed in certain cases.

Investigations have shown that the hexagon socket of the blind screws does not meet the specifications in some cases. Furthermore, in a few cases deviations were identified in the internal thread of the tibial component, in which the blind screws are delivered pre-assembled.
In combination, these two problems can lead to the screw not being able to be loosened intraoperatively. This is caused by manufacturing process deficiencies.

2.2 Hazard giving rise to the FSCA*:

Prolongation of surgery due to intraoperatively change in procedure, probably to cementing technique.

2.3 Probability of problem arising:

The problem only occurs if an optional uncemented Tilastan Proximal Tibial Spacer or Proximal Tibial Segment has to be used. The probability of the problem arising is considered to be occasional.

2.4 Predicted risk to patient/users:

There is no increased risk if the added modified surgical technique with the cementing technique for Tilastan Proximal Tibial Spacers or Segments is followed correctly.

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

Waldemar Link received 4 complaints within the last months regarding screws that could not be removed from the tibial component.

2.7 Other information relevant to FSCA:

The enclosed cementing technique is described in the literature and is an alternative to screwing the spacers and segments.
The change to the cementing technique of the spacers and segments made of Tilastan corresponds to a standard procedure used for UHMWPE spacers and segments.
In the long term, the cementing technique will be included as an optional procedure in our standard surgical techniques.

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

- Please return the reply form to us in any event until the **17 June 2024** as documentation of the Field Safety Corrective Action.
- Please ensure that all users of the above products within your organization and other relevant persons have been notified of this safety information. If you have transferred the products to third parties please pass on a copy of this information or notify the contact person indicated below.

3.2 By when should the action be completed ?:

17 June 2024

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 increased risk if the added modified surgical technique with the cementing technique for Tilastan Proximal Tibial Spacers and Segments is followed correctly.

3.4 Is customer Reply Required ?* :

☒ Yes, until: 17.06.2024
☐ 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 ?

- The adapted surgical technique will be provided from **22.05.2024**.
- The customer reply forms will be checked by **30.06.2024**.
- A reminder will be sent to outstanding customers.
- Completion will take place as soon as all reply forms have been received, estimated by **30.07.2024**.

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

☐ Yes
☒ No

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 ?

N/A

4. General Information

4.1 FSN Type*:

☐ New ☒ Update

4.2 For updated FSN

Reference number of previous FSN **R-2022-01**
Date of previous FSN: **23.05.2022**

Description of the product problem of previous FSN:
There is a risk that the blind screws of the modular tibial component cannot be loosened intraoperatively. This is necessary if an uncemented Tilastan proximal spacer is to be screwed in which is only needed in certain cases. Investigations showed that the release torque after assembly of the blind screw does not meet the specifications. This is caused by a manufacturing process deficiency.

Affected products of previous FSN:
All after manufacturing date 2021-08 until manufacturing date 2022-05

4.3 For updated FSN, key new information as follows:

Due to new complaints about the same problem, a correction and preventive measure was initiated. Further specification deviations were identified in the manufacturing process. We therefore need to inform you once again and draw your attention to the alternative surgical technique.

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

☐ Yes ☒ No

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/de/
Single Registration Number (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:

Modified additional surgical technique

4.10 Name/Signature:

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

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.