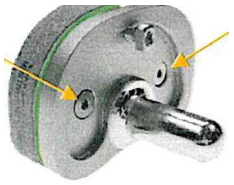
FSN Ref.: R-2022-01
23.05.2022

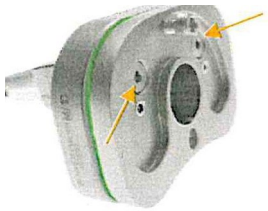
URGENT FIELD SAFETY NOTICE

Device Commercial Name:

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



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



For Attention of*:

Distributor / Local branch of manufacturer

Hospita!

Contact details of local representative*:

Responsible Person
Dr. Poroshat Khalilpour
Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany
E-Mail: vigilance@linkhh.de
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 of
Endo-Model-M Modular Knee Prosthesis System

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

1.3 Unique Device Identifier (EU UDI-DI):

N/A

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 dated 2021-08 **until** manufacturing dated 2022-05

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 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.

2.2 Hazard giving rise to the FSCA*:

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

2.3 Probability of problem arising:

The problem only occurs if an optional uncemented Tilastan proximal spacer has to be used.

2.4 Predicted risk to patient/users:

There is no increased risk if the added modified surgical technique with the cementing techni ue for Tilastan roximal s acers is followed correct!

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

Waldemar Link received eleven complaints within the last month regarding screws that could not be removed from the modular tibial com onent.

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

- Please return the fax reply to us in any event until the **10 June 2022** 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 ?:

10 June 2022

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 spacers is followed correctly.

3.4 Is customer Reply Required ?* :

Yes, until: 10.06.2022 ☐ 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 June 2022

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 ?

N/A

4. Genera! 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 tor follow-up

FSN: N/A

4.7 Manufacturer information:

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany
https:llwww.linkorthopaedics.com/
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:

1 Modified additional surgical technigue

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)

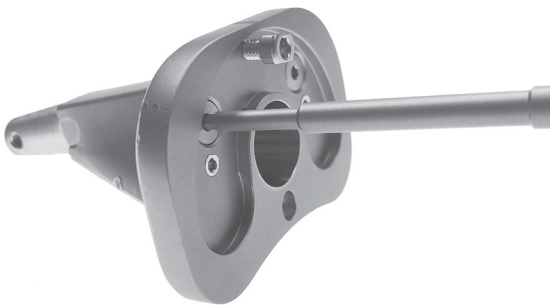
Please maintain awareness on this notice and resulting action tor an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authoritv if appropriate, as this provides important feedback.

Important Information

If a Tilastan proximal spacer is to be used and either one or both blind screws of the modular tibial component cannot be loosened, then the following modified surgical technique is to be performed.

Endo-Model SL



✕ = screw removal impossible?

It has to be observed that a homogenous cement mantle between the Tilastan proximal spacer (full & half) and modular tibial component is ensured. The cement mantle should be 1-2 mm thick.

Waldemar Link GmbH & Co. KG
Barkhausenweg 10 · 22339 Hamburg · Germany, Phone +49 40 53995-0 · info@linkhh.de
www.linkorthopaedics.com

Important Information

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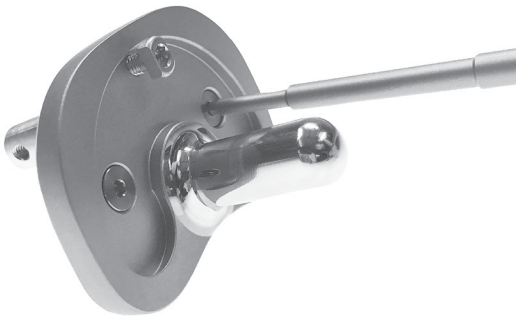
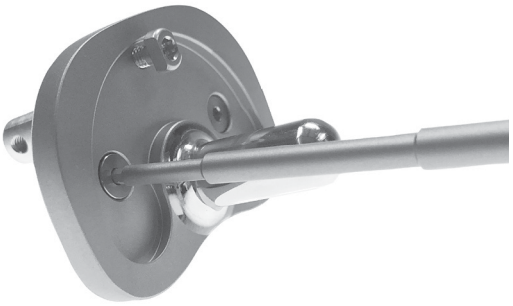
Endo-Model – M





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