FSN Ref.: R-2023-11
22. November 2023

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Device Commercial Name:

Endo-Model Patella Glide Resection Guide, large - Instrument

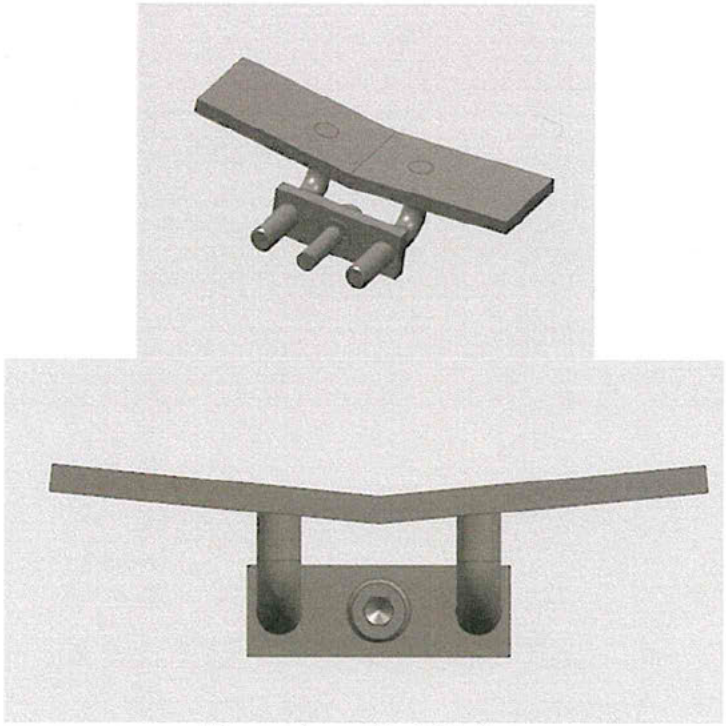

Figure 1 and 2 - 3D view

For Attention of*:

☒ Distributor / Local branch of manufacturer
☒ Hospital

Contact details of local representative*:

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

Risk addressed by FSN

1. Information on Affected Device

1.1 Device Type*:

Endo-Model Patella Glide Resection Guide, large - Instrument

1.2 Commercial name:

Endo-Model Hinge Knee Prosthesis Patella Glide Resection Guide attachable to right and left Femoral Saw Guides, large Stainless Steel

1.3 Unique Device Identifier (EU UDI-DI):

04026575245253

1.4 Primary clinical purpose of device*:

The Instrument is designed for the implantation of the Endo-Model Knee System.

The Patella Glide Resection Guide is used to resect the anterior surface of the distal femur into the correct shape for the implant.

1.5 Article number(s)*:

15-2530/05

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

C306165

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

We have noticed internally that the direct part marking of the Patella Glide Resection Guide "small-medium" incorrectly reflects “large”. The individual components were mixed up during the commissioning process, which led to this error pattern during the manufacturing process.

2.2 Hazard giving rise to the FSCA*:

Due to the incorrectly combined components the angle and height do not correspond to the specifications. As a result, too little bone material is resected and the trial prosthesis cannot be fitted correctly. Consequently, the user has to resect the excess bone material by hand, which can lead to an extension of the surgery time.

2.3 Probability of problem arising:

The probability of occurrence that the bone cannot be resected as planned is classified as high for the affected LOT.

2.4 Predicted risk to patient/users:

The surgical time may be extended because too little bone material is resected during the bone resection. During the subsequent manual postoperative preparation performed according to the surgical technique, the surgery time may be slightly extended as more bone material has to be resected. No further risk to the patient or user is to be expected.

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

See point 2.1

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

- Should you have any of the affected product in your inventory, please destroy the products.
- 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.
- We would be grateful if you could return the fax reply to us in any event until the **08. December 2023** 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.

3.2 By when should the action be completed ?:

05. January 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

During the preparation, the femur is prepared on the basis of the trial prosthesis so that the final implant has an optimal fit.

3.4 Is customer Reply Required ?* :

☒ Yes, until: 08. December 2023 ☐ 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 ?

05. January 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

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.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:

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-2023-11
22. November 2023

Field Safety Notice
Distributor / Importer Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2023-11
FSN Date*	22. November 2023
Product / Device name*	Endo-Model Patella Glide Resection Guide, large
Product Code(s)	15-2530/05
Batch / Serial Number(s)	C306165

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:	
☐ I have destroyed affected devices [Enter number destroyed and date complete]	Qty:	Lot/Serial Number(s):	Date Destroyed:
	N/A:	Comments:	

☐ Affected devices are not available for return / destruction (e.g. implanted) [Enter number implanted and date]	Qty:	Lot/Serial Number(s):	Date Implanted:
	N/A:	Comments:	
☐ Neither I nor any of my customers has any affected devices in inventory			
Print Name*	Distributor/Importer print name here:		
Signature*	Distributor/Importer sign Here:		
Date*			

4. Return acknowledgement to sender

E-Mail	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 - 784
Postal Address	WALDEMAR LINK GmbH & Co. KG Barkhausenweg 10 22339 Hamburg Germany
Web Portal	https://www.linkorthopaedics.com/
Fax	**+49 40 539 95 – 174**
Deadline for returning the Distributor / Importer reply form*	08. December 2023

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.