FSN Ref.: R-2025-02
24.03.2025

URGENT FIELD SAFETY NOTICE – Advisory Notice

Device Commercial Name:

LinkSymphoKnee Femoral and Tibial Augments

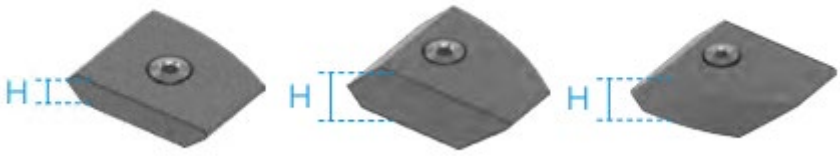

Figure 1: Example pictures - LinkSymphoKnee Femoral Augments - distal

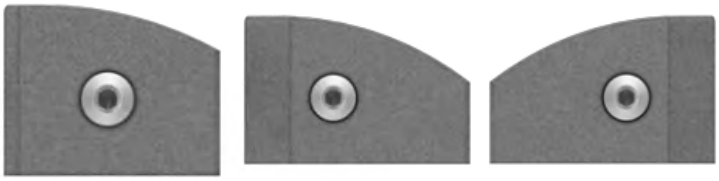

Figure 2: Example pictures - LinkSymphoKnee Femoral Augments - distal

Figure 3: Example pictures – LinkSymphoKnee Tibial Augments

Figure 4: Example pictures – LinkSymphoKnee Tibial Augments

For Attention of*:

☒ Distributor / Local branch of manufacturer
☒ Hospital

Contact details of local representative*:

Responsible Person (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*:

LinkSymphoKnee Femoral and Tibial Augments

1.2 Commercial name:

LinkSymphoKnee
- Femoral augments - distal
- Femoral augments - posterior
- Femoral augments - L-shaped
- Tibial augments

1.3 Unique Device Identifier (EU UDI-DI):

Femoral augments - distal	Femoral augments - posterior	Femoral augments - L-shaped	Tibial augments
04026575284931	04026575257539	04026575258048	04026575258192
04026575257102	04026575257546	04026575258055	04026575258208
04026575257133	04026575257607	04026575258062	04026575258215
04026575257140	04026575257584	04026575258079	04026575258222
04026575257171	04026575257621	04026575258086	04026575258246
04026575257188	04026575257645	04026575258109	04026575258253
04026575257195	04026575257669	04026575258123	04026575258260
04026575257201	04026575257690	04026575258147	04026575258277
04026575257256	04026575257768	04026575258154	04026575258284
04026575257263	04026575257775	04026575258161	04026575258291
04026575257270	04026575257782	04026575258178	04026575258307
04026575257287	04026575257799	04026575258185	04026575258314
04026575257379	04026575257843		04026575258321
04026575257386	04026575257850		04026575258338
04026575257393	04026575257867		04026575258345
04026575257409	04026575257881		04026575258352
04026575257454	04026575257942		04026575258369
04026575257461	04026575257959		04026575258376
04026575257478	04026575257966		04026575258383
04026575257485	04026575257973		04026575258390
			04026575258406
			04026575258413
			04026575258420
			04026575258437
			04026575258475
			04026575258505
			04026575258529
			04026575258536
			04026575258543
			04026575258550

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable LinkSymphoKnee 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 knee system forms a total replacement of the knee joint when combined with the femoral-, tibial- and polyethylene plateau. The LinkSymphoKnee can be used with full-grown, anesthetized patients of any ethnic origin and sex. The LinkSymphoKnee can be implanted with and without cement. 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 orthopaedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.
In addition, there is a selection of femoral and tibial stems and augments, which can be used in conjunction with the modular version of the femoral and tibial components.
The LinkSymphoKnee CCK configuration consists of a modular CCK femoral component, which can be used in conjunction with several femoral stem and augment components. The CCK articulating surface component is used in conjunction with the modular tibial component, which allows for the use of tibial stems and augments.

1.5 Article number(s)*:

Femoral augments - distal	Femoral augments - posterior	Femoral augments - L-shaped	Tibial augments
880-300/11	880-310/11	880-320/12	880-331/11
880-300/21	880-310/21	880-320/22	880-331/12
880-301/11	880-311/11	880-321/12	880-331/13
880-301/21	880-311/21	880-321/22	880-331/21
880-303/11	880-313/11	880-323/13	880-331/22
880-303/12	880-313/12	880-323/23	880-331/23
880-303/21	880-313/21	880-325/13	880-333/11
880-303/22	880-313/22	880-325/23	880-333/12
880-305/11	880-315/11	880-327/13	880-333/13
880-305/12	880-315/12	880-327/23	880-333/21
880-305/21	880-315/21	880-329/13	880-333/22
880-305/22	880-315/22	880-329/23	880-333/23
880-307/11	880-317/11		880-335/11
880-307/12	880-317/12		880-335/12
880-307/21	880-317/21		880-335/13
880-307/22	880-317/22		880-335/21
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880-309/12	880-319/12		880-335/23
880-309/21	880-319/21		880-337/11
880-309/22	880-319/22		880-337/12
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			880-339/23

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

Manufacturing date up to and including March 2025 [All until 2025-03-01]. There is only a remote/rare probability that the listed Augments are affected.

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

Due to a complaint we have been notified that a LinkSymphoKnee Femoral Augment was delivered with a preassembled Femoral Augment screw that was missing a thread. As a result the Femoral Augment could not be fixed to the Femoral Component as intended. A different screw from another Femoral Augment was used intraoperatively instead.

Figure 5: Example picture of Femoral Augment screw without thread

2.2 Hazard giving rise to the FSCA*:

Prolongation and modification of surgery due to intraoperative change in procedure.

2.3 Probability of problem arising:

The occurrence of failure is remote.

2.4 Predicted risk to patient/users:

It is not to be assumed that a defective Femoral / Tibial Augment screw can be screwed in. The error would be noticed during surgery, at the latest while trying to screw in the Augment screw.

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

Waldemar Link received one complaint regarding this error pattern where a missing thread could be confirmed in a Femoral Augment screw. Three further complaints with a positioning problem of the Femoral Augment screw were received without sufficient information about the screw thread.
Two Femoral Augment screws and one Tibial Augment screw with a missing thread were found during inspection of the sales warehouse.

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: see following

Immediate risk reduction:

- In the remote case of a malfunctioning preassembled Augment screw, open an alternative Augment and use the screw. Alternative sizes of Augments are always available in the operating room during the surgery. For all Femoral Augment sizes and types the same long screw type is preassembled and for all Tibial Augments the same short screw type is preassembled, see table 1.

Augment	**Associated screw**
Tibial Augment	Tibial Augment screw, short
Femoral Augment, distal	Femoral Augment screw, long
Femoral Augment, posterior	
Femoral Augment, L-Shaped	

Table 1: Combination table – Augments and associated screws

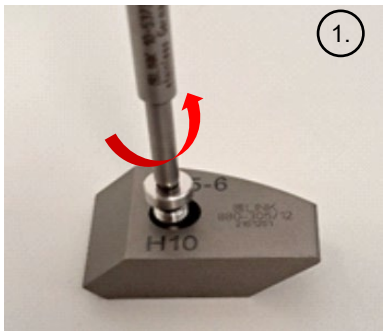
Long term risk reduction:

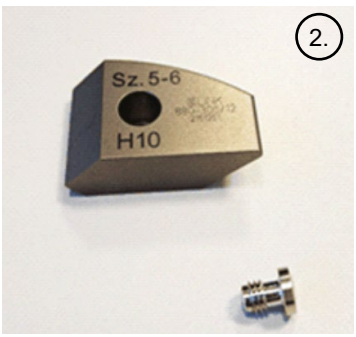
- LINK will provide two sterilized replacement screws for Femoral Augments and two for Tibial Augments for each affected hospital as a back-up for upcoming surgeries.
- Use provided sterilized replacement screws in the remote case of a malfunctioning preassembled Augment screw.

Instructions for disassembling and replacing a defective screw:

Disassembly

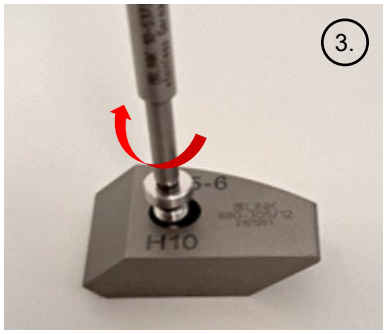
1. Use the 2,5 mm Torque Wrench article REF (15-2545) to unscrew the screw from the Augment while pushing the tip of the screw towards the Augment
2. Exchange the screw

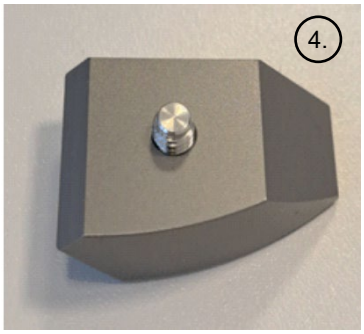




Assembly/Replacement

3. Use the 2,5 mm Torque Wrench article REF (15-2545) to screw in the screw into the Augment
4. The screw head must be countersunk in the Augment and the screw tip must protrude. For further procedure follow the surgical technique of the LinkSymphoKnee.





- 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 **07.04.2025** as documentation of the Field Safety Corrective Action. This applies even if you have none of the listed products in stock.

3.2 By when should the action be completed?:

07.04.2025 – Return of reply form

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

☒ No, because: The probability of detection is high – It is not to be assumed that a defective Femoral / Tibial Augment screw can be screwed in. The error would be noticed during surgery, at the latest while trying to screw in the Femoral / Tibial Augment screw.

3.4 Is customer Reply Required?*:

☒ Yes, until: 07.04.2025 ☐ No

3.5 Action being taken by the manufacturer:

☐ Product Removal
☐ On-site device modification / inspection
☐ Software upgrade
☐ IFU or labelling change
☒ Other:
☐ None

- Provide instructions for immediate risk reduction:
  In the remote case of a malfunctioning preassembled Femoral / Tibial Augment screw, open an alternative Femoral / Tibial Augment and use the screw. Alternative sizes of Femur / Tibial Augments are always available in the operating room during the surgery. For all Femoral Augments sizes and types the same long screw type is preassembled and for all Tibial Augments sizes and types the same short screw type is preassembled, see table 1.

- Provide solution for long term risk reduction:
  LINK will provide two sterilized replacement screws for Femoral Augments and two for Tibial Augments for each affected hospital as a back-up for upcoming surgeries.

3.6 By when should the action be completed?

Customers will be informed about FSN and solution for immediate risk reduction within 2 weeks.
Replacement screws will be provided within the upcoming weeks, by end of April 2025 at the latest, for long term risk reduction.
The FSCA will be completed within approximately 8 weeks.

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. 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:

Annerike-Tizia Hucklenbroch

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.