FSN Ref.: R-2023-09
24.07.2023

URGENT FIELD SAFETY NOTICE – Product Advisory Notice with subsequent Recall

Device Commercial Name:

Link OptiStem, Rasp Handle Stainless Steel

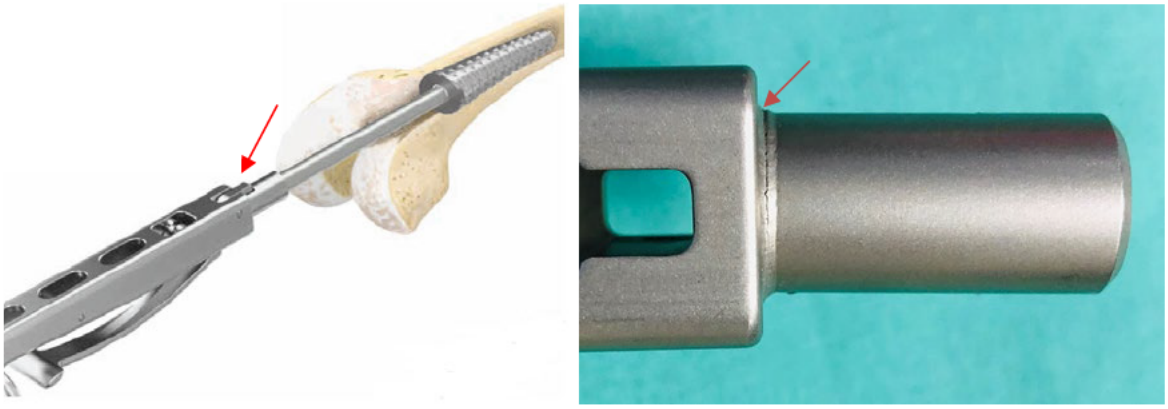


Figure 1: Affected product - Article REF 17-5220/01

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

[redacted]

Risk addressed by FSN

1. Information on Affected Device

1.1 Device Type*:

Link OptiStem, Rasp Handle Stainless Steel

1.2 Commercial name:

Link OptiStem, Rasp Handle Stainless Steel

1.3 Unique Device Identifier (EU UDI-DI):

04026575284658

1.4 Primary clinical purpose of device*:

The Link OptiStem (in short OptiStems) is an expansion of the modular stem portfolio. Link OptiStem consists of a Modular Stem, Adapter and Fixation Screw. The OptiStems intend a lumen filling positioning in the distal femur in (re-)revision surgery. The OptiStem Modular Stems follow an intramedullary self-positioning. The OptiStems allow an intraoperative choice and adjustment of leg length and rotation via the OptiStem Adapter and its rotational alignment between the Modular Stem/ Adapter interface. After assembling the OptiStems they have to be joined and implanted in combination with the Femoral Components of Endo-Model SL Knee Joint Prosthesis or LINK Endo-Model EVO –M / –W.

The provided instrument sets for Link OptiStem allow an appropriate preparation of the tibial and femoral bone including a knee trial reposition.
The OptiStem rasp handle must be assembled with the OptiStem raps in the selected length.

Medullary canal preparation
The rasp is fitted to the handle. Starting with the smallest size and shortest length, the rasp is introduced into the femoral canal, and driven in with suitably gentle mallet blows so as to avoid fracturing the stem. Then the medullary canal can be prepared with the next larger rasp until a satisfactory position with cortical contact is achieved. The rasp remains in situ.

In addition, the Link OptiStem rasp handle is also used in some cases for custom-made products offered by CustomLink.

[redacted]

1.7 Affected serial or lot number range:

C010108
C151519

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

It was noticed that the weld in the frontal area of the instruments of the current version may not last the full planned lifetime.

Since we like to ensure that scheduled surgeries are performed and patients are provided with desired prostheses (Link OptiStem or CustomLink) we will for safety reasons and **immediate action** provide **2 rasp handles** for the planned surgeries **until replacement** with **optimized rasp handles** is available and these products are recalled. See 4.4

If you notice a crack on the weld during surgery, please use the second rasp handle for completion of the bone preparation.

Please have both rasp handles sterilized for surgery and make sure the inspection prior use according to IFU H50 is conducted properly.

2.2 Hazard giving rise to the FSCA*:

If a crack in the weld of the rasp handle is not taken seriously it may lead to a fracture of the frontal sleeve when the rasp is further impacted or extracted. The rasp remains intact. The rasp needs to be pulled out by a clamp leading to a prolongation of surgery or modified surgery.

2.3 Probability of problem arising:

The occurrence of a weak weld is almost certain, but the occurrence of a risk to the patient is remote. The risk to the patient is reduced by a second provided rasp handle to be used for the first rasp as immediate action and interim solution.

2.4 Predicted risk to patient/users:

See 2.2

2.5 Further information to help characterize the problem:

If you notice a crack on the weld during surgery, please use the second rasp handle for completion of the bone preparation.

2.6 Background on Issue:

Waldemar Link received one complaint regarding a fractured weld during surgery. No consequence to the patient was reported.

[redacted] **FSCA:**

the rasp handle will take place as soon as the new version ill then be published with the recall date.

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

- Since we like to ensure that scheduled surgeries are performed and patients are provided with desired prostheses (Link OptiStem or CustomLink) we will for safety reasons and immediate action provide 2 rasp handles for the planned surgeries until replacement is available.
- If you notice a crack on the weld during surgery, please use the second rasp handle for completion of the bone preparation.

3.2 By when should the action be completed ?:

Since 11.07.2023, customers are provided with 2 rasp handles and informed accordingly.

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

No, as the FSN affects an instrument.

3.4 Is customer Reply Required ?* :

☒ Yes, within **2 weeks** after receipt of the FSN.

[redacted]

3.5 Action being taken by the manufacturer

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

- Waldemar Link GmbH & Co. KG will for safety reasons and immediate action provide 2 rasp handles for the planned surgeries until replacement is available
- We will inform you as soon as we can replace the instruments by optimized ones.
- Please ensure to have 2 rasp handles available for each surgery. Should there be any additional need, please contact us.
- After surgery, please return both rasp handles immediately.

3.6 By when should the action be completed ?

31.10.2023 see 4.6

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

[redacted]

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 ?:

Date and information regarding product recall and replacement.

4.6 Anticipated timescale for follow-up FSN:

3 months

4.7 Manufacturer information:

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany
https://www.link-ortho.com
Single Registration Number (EU SRN-No.): DE-MF-000005215

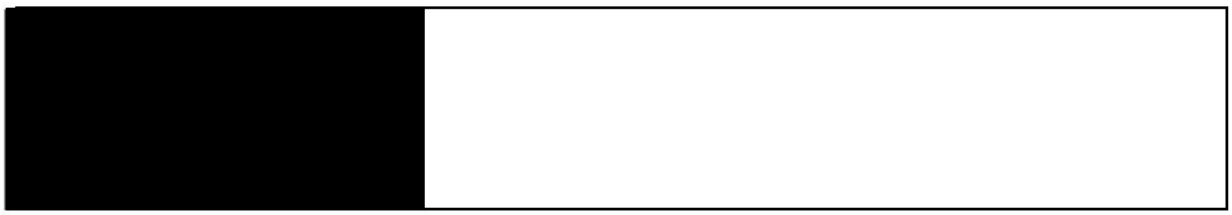
4.8 The Competent (Regulatory) Authority of your country (EU) has been informed about this communication to customers. *:

☒ 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.