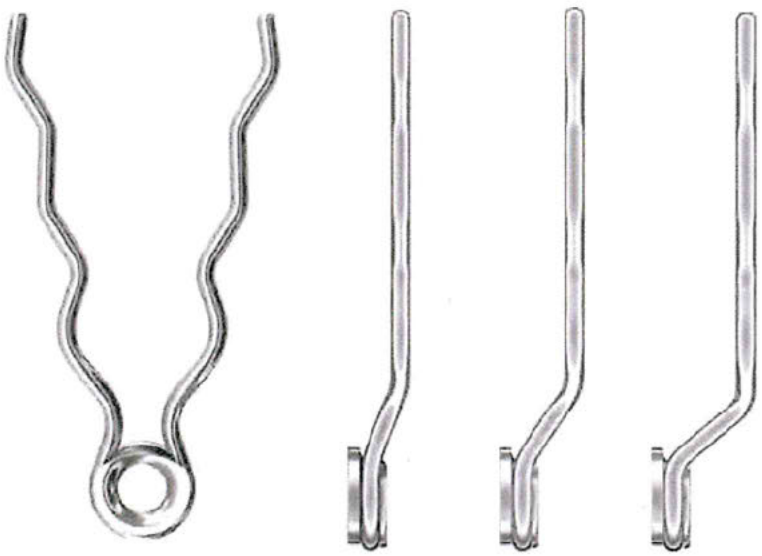
FSN Ref.: R-2023-02
15 March 2023

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Device Commercial Name:

Stoffella DC Hallux Splint - Link Stoffella Internal Hallux Fixator



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*:

Stoffella DC Hallux Splint

1.2 Commercial name:

Stoffella DC Hallux Splint, Link Stoffella Internal Hallux Fixator bayonet 3 mm, sterile, Stainless Steel

1.3 Unique Device Identifier (EU UDI-DI):

04026575400096

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable LINK Internal Hallux Fixator manufactured by Waldemar Link GmbH & Co. KG is intended to correct a hallux valgus deformity by subcapital angular osteotomy of the first metatarsal bone. The LINK Internal Hallux Fixator can be used with full-grown, anesthetized patients of any ethnic origin and sex. The LINK Internal Hallux Fixator is implanted 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 orthopedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products or in non-sterile condition on appropriate trays.

1.5 Article number(s)*:

99-0068/53

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

2125268

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

It has come to our attention that the offset/bayonet of the Stoffella DC-Hallux Splint is 5 mm instead of the intended 3 mm. A production order of 101 parts is affected.

2.2 Hazard giving rise to the FSCA*:

A greater offset/bayonet of the splint may result it greater lateralization of the condyle and overcorrection may occur.

2.3 Probability of problem arising:

The probability is considered low because the splint is inserted into the shaft of the metatarsal and the surgeon can counteract overcorrection by positioning the splint in the medullary canal.

2.4 Predicted risk to patient/users:

The risk for the patient of overcorrection of the hallux is low because the surgeon can counteract overcorrection during the surgery.

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

We have received one complaint regarding this error pattern.

2.7 Other information relevant to FSCA:

To date, no further complaints have been registered regarding this error pattern.

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 send the products back to Waldemar Link GmbH & Co. KG.
- 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 **31 March 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 ?:

In any case, please contact us for documentation of the FSN until **31 March 2023** and return the affected devices. This also applies if you do not currently have any articles of the affected batch in your stock.

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

We recommend continuing with the patient's regular follow-up.

3.4 Is customer Reply Required ?* :

☒ Yes, until: 31 March 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 ?

30 April 2023

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.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:

Distributor Reply Form

4.10 Name/Signature:

[redacted]

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-2023-02
15. March 2023

Field Safety Notice
Distributor / Importer Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2023-02
FSN Date*	15. March 2023
Product / Device name*	Stoffella DC Hallux Splint, Link Stoffella Internal Hallux Fixator bayonet 3 mm, sterile, Stainless Steel
Product Code(s)	99-0068/53
Batch / Serial Number(s)	2125268

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
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.link-ortho.com
Fax	**+49 40 539 95 – 174**
Deadline for returning the Distributor / Importer reply form*	31. March 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.