FSN Ref.: R-2024-01
22.01.2024

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Device Commercial Name:

BiMobile Dual Mobility System, Liner

Figure 1: Example of affected product label **REF** 184-280/12 **LOT** 2325426

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

Risk addressed by FSN

1. Information on Affected Device

1.1 Device Type*:

BiMobile Dual Mobility System

1.2 Commercial name:

BiMobile Dual Mobility System, Liner

1.3 Unique Device Identifier (EU UDI-DI):

04026575230747, 04026575174782

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable BiMobile Dual Mobility System manufactured by Waldemar Link GmbH & Co. KG is intended for long-term replacement of the acetabular side of a diseased and / or defective hip joint in the human body. The BiMobile Dual Mobility System forms a total replacement of the hip joint when combined with the prosthesis head and prosthesis stem. The BiMobile Dual Mobility System can be used with full-grown, anesthetized patients of any ethnic origin and sex. The BiMobile Dual Mobility System is 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 orthopedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.

BiMobile Dual Mobility System – Liner
The BiMobile Dual Mobility Liner is available in two different materials: Standard UHWMPE and E-Dur Liner.

The Dual Mobility (DM) insert is a metal, EndoDur, insert / adapter, that transforms the MobileLink Acetabular Cup System into a dual mobility cup. The DM insert / adapter is to accommodate poly DM liners from the BiMobile Dual Mobility System.

1.5 Article number(s)*:

184-280/12, 184-260/12

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

184-280/12 LOT 2339039 LOT 2334253 LOT 2325426	184-260/12 LOT 2219070

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

On the affected labels of the BiMobile Liner there is an incorrect letter “F” referring to the compatible size of the MobileLink Dual Mobility Insert. The label should instead provide information for the compatibility to size "G". The brown color coding on the main label and the inner patient label have correct information size “G”. This information is only relevant for the combination of MobileLink Dual Mobility insert with BiMobile Dual Mobility System Liner.

2.2 Hazard giving rise to the FSCA*:

There is a risk because the label does not show the correct letter “G” referencing to the compatibility of the components. This may lead to confusion during surgery and a prolonged or modified surgery. A MobileLink Dual Mobility insert size “F” could not be combined with the affected liners with article REF 184-280/12 and REF 184-260/12, as these were too large.

2.3 Probability of problem arising:

The occurrence of an incorrect label is almost certain, but the occurrence of a risk to the patient is moderate if a combination with MobileLink Dual Mobility Insert is planned. The surgeon either chooses the correct product by article REF and color code or the surgeon identifies the non-conformity during assembly if he chooses by letter “F”. This case leads to a prolonged or modified operation.

2.4 Predicted risk to patient/users:

See 2.2

2.5 Further information to help characterize the problem:

As confusion arises the surgeon has the possibility to check the options for combination in the surgical technique by article REF. In addition, patient labels inside the packaging are correct.

2.6 Background on Issue:

Waldemar Link received one complaint regarding a discrepancy between the label and surgical technique which was identified prior to use.

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 send the products back to Waldemar Link GmbH & Co. KG.
- Should you have any question on acquiring alternative components 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 **31.01.2024** 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 ?:

29.02.2024

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

☐ Yes , the following: ☒ No, because
Patients treated with a combination of only BiMobile components, were treated correctly. The inner patient labels are correct.

3.4 Is customer Reply Required ?* :

☒ Yes, until: **31.01.2024** ☐ 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 ?

29.02.2024

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 ?

No, as the information provided is considered sufficient.

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:

Customer Reply-Form
Distributor Reply-Form

4.10 Name/Signature:

Dr. Poroshat Khalilpour

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.

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL
Distributor / Importer Reply Form

1. Field Safety Notice information

FSN Reference number*	R-2024-01
FSN Date*	22.01.2024
Product / Device name*	BiMobile Dual Mobility System - Liner
Product Code	184-280/12, 184-260/12
Batch / Serial Number(s)	184-280/12 LOT 2339039 LOT 2334253 LOT 2325426 184-260/12 LOT 2219070

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 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 returned affected devices [Enter number of devices returned and date complete]	Qty:	Lot/Serial Number(s):	Date Returned:
☐ Affected devices are not available for return as already implanted. [Enter number implanted and date]	Qty:	Lot/Serial Number(s):	Date Implanted:

Print Name*	Distributor/Importer print name here:
Signature*	Distributor/Importer sign Here:
Date*	

4. Return acknowledgement to sender

Email	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 - 432
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 January 2024**

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.