FSN Ref.: R-2023-08
14.07.2023

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Device Commercial Name:

MobileLink Acetabular Cup System, Shell/Insert Adapter

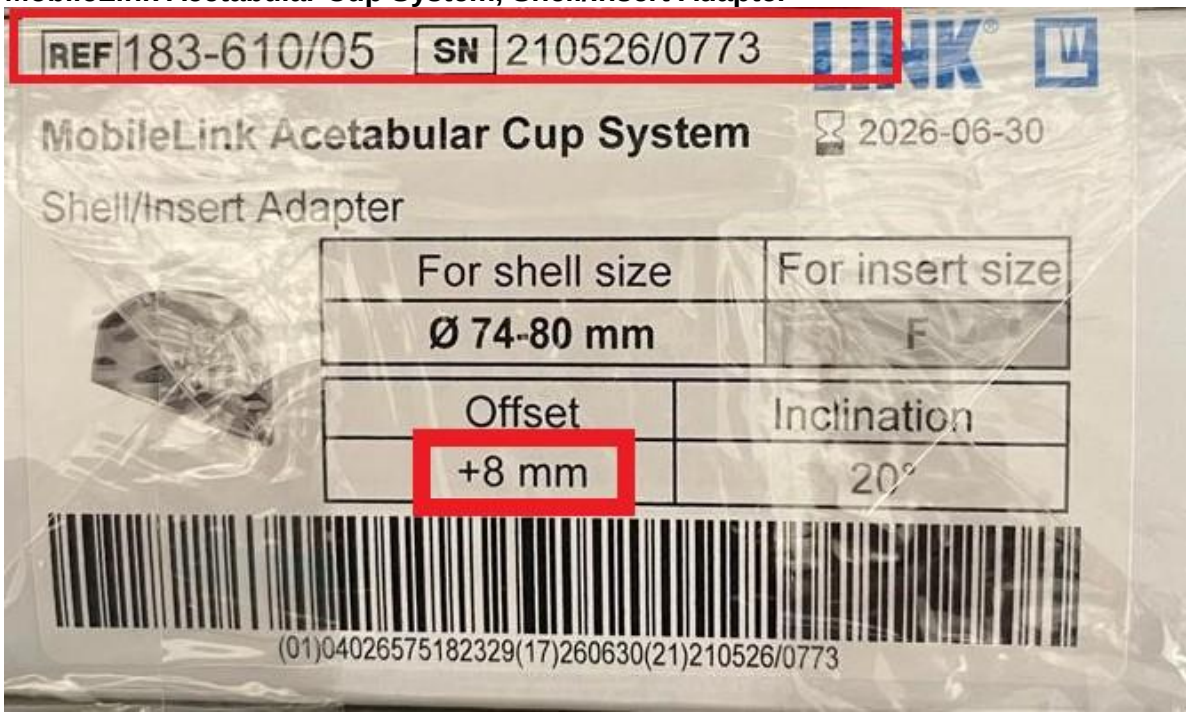

Figure 1: Example of affected product label REF 183-610/05 SN 210526/0773

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*:

MobileLink Acetabular Cup System, Shell/Insert Adapter

1.2 Commercial name:

Shell/Insert Adapter for Shell 74-80 mm, Insert Size F, + 12 mm Offset 20° Inclination, Tilastan

1.3 Unique Device Identifier (EU UDI-DI):

04026575182329

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable MobileLink Acetabular Cup 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 MobileLink Acetabular Cup System forms a total replacement of the hip joint when combined with the prosthesis head and stem. The MobileLink Acetabular Cup System can be used with full-grown, anesthetized patients of any ethnic origin and sex. The MobileLink Acetabular Cup System is implanted without cement. The Shell/Insert Adapters are metal, Tilastan, inserts, that are inserted into the shells and are to accommodate the UHMWPE or ceramic inserts. They are used to adjust or change the inclination of the cup entry plane and/or offset of the center of rotation in a fixed shell. 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.

1.5 Article number(s)*:

183-610/05

1.6 Software version:

N/A

1.7 Affected serial or lot number range:

All SN with manufacturing date before 2023-06-01

220413/0084	160720/0232	210526/0771
220413/0085	160720/0233	210526/0772
220413/0086	160720/0234	210526/0773
220413/0087	160720/0235	210526/0774
220413/0088	160720/0236	210526/0775
220413/0089	160720/0237	210526/0776
220413/0090	160720/0238	210526/0777
220413/0091	160720/0239	210526/0778
220413/0092	160720/0240	210526/0779
220413/0093	160720/0241	210526/0780
	160720/0242	210526/0781
	160720/0243	210526/0782
	160720/0244	210526/0783
	160720/0245	210526/0784
	160720/0246	210526/0785
	160720/0247	210526/0788

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

Due to a complaint, it has come to our attention that the offset on the labels of the Shell/Insert Adapter does not match to the article REF and the description in the surgical technique. This only affects the article REF 183-610/05.
For these products it should be +12 mm offset on all labels including the label for the implant card, but the Shell/Insert Adapter were incorrectly labelled as + 8 mm offset.
The product in the packaging has a +12 mm offset, which is correct and fits to the article REF and the description of the surgical technique.

2.2 Hazard giving rise to the FSCA*:

There is a risk because the label does not show the correct offset. This may lead to confusion during surgery and a prolonged surgery.
For patients who have already been treated due to planned and conducted surgery according to the article REF an incorrectly offset in the implant card could lead to confusion during a revision.
We assume that the surgeon plans the surgery with article REF and therewith chooses the correct item for the surgery.

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 unlikely, as the surgeon either chooses the correct product by article REF or inclination which is correct.

2.4 Predicted risk to patient/users:

See 2.2

2.5 Further information to help characterize the problem:

N/A

2.6 Background on Issue:

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

2.7 Other information relevant to FSCA:

For patients who have already been treated, the implant card needs to be corrected manually: +12 mm instead of +8 mm offset.

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.
- For patients who have already been treated, the implant card needs to be corrected manually to reflect the correct offset to +12 mm.
- Please return the reply form to us in any event until the **31.07.2023** 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 ?:

31.07.2023

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

☒ Yes , the following: ☐ No, because
For patients who have already been treated, the implant card needs to be corrected manually to reflect the correct offset to +12 mm.

3.4 Is customer Reply Required ?* :

☒ Yes, until: **31.07.2023** ☐ 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 ?

30.08.2023

3.7 Is the FSN required to be communicated to the patient /lay user ?

☒ Yes ☐ No ☐ N/A
For patients who have already been treated

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:

N/A

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.