FSN Ref.: R-2024-03
06.02.2024

URGENT FIELD SAFETY NOTICE – Advisory Notice

Device Commercial Name:

SPII Model Lubinus - Hip Prosthesis Stem

This Advisory Notice is intended to provide additional guidance on **how to read the label** correctly, please see examples in Figure 1 and 2:

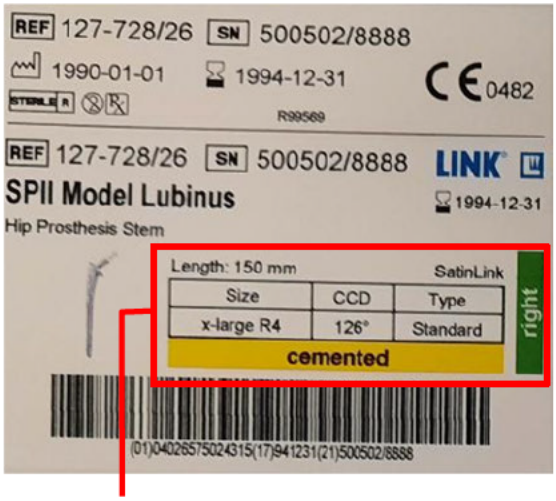

Figure 1:
The column with the header "Size" refers to the stem width: x-large R4
The column with the header "Type" refers to the neck length: Standard

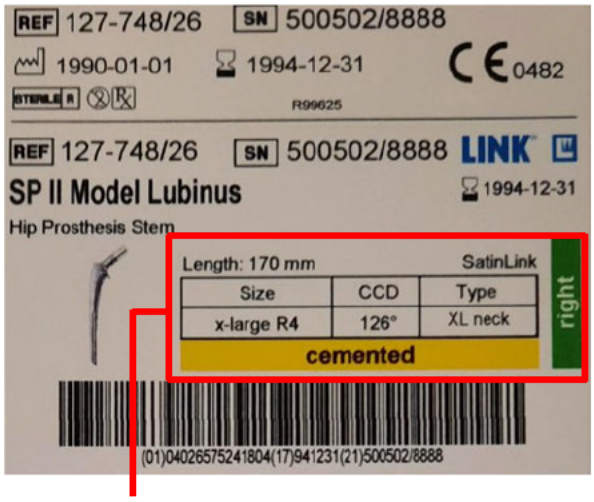

Figure 2:
The column with the header "Size" refers to the stem width: x-large R4
The column with the header "Type" refers to the neck length: XL neck

For Attention of*:

- ☒ Distributor / Local branch of manufacturer
- ☒ Hospital

Contact details of local representative*:

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*:

SPII Model Lubinus, Hip Prosthesis Stem

1.2 Commercial name:

SPII Model Lubinus, Hip Prosthesis Stem

1.3 Unique Device Identifier (EU UDI-DI):

SPII Model Lubinus, Hip Prosthesis Stem Standard Neck, cemented

Article REF	UDI - DI
127-610/17	04026575387168
127-610/26	04026575387304
127-610/35	04026575387441
127-612/17	04026575387175
127-612/26	04026575387311
127-612/35	04026575387458
127-614/17	04026575387182
127-614/26	04026575387328
127-614/35	04026575387465
127-616/17	04026575387199
127-616/26	04026575387335
127-616/35	04026575387472
127-618/17	04026575387205
127-618/26	04026575387342
127-618/35	04026575387489
127-620/17	04026575387212
127-620/26	04026575387359
127-620/35	04026575387496
127-622/17	04026575387229
127-622/26	04026575387366
127-622/35	04026575387502
127-624/17	04026575387236
127-624/26	04026575387373
127-624/35	04026575387519
127-626/17	04026575387243
127-626/26	04026575387380
127-626/35	04026575387526
127-628/17	04026575387250
127-628/26	04026575387397
127-628/35	04026575387533
127-630/17	04026575387267
127-630/26	04026575387403
127-630/35	04026575387540
127-632/17	04026575387274
127-632/26	04026575387410
127-632/35	04026575387557
127-634/17	04026575387281
127-634/26	04026575387427
127-634/35	04026575387564
127-636/17	04026575387298
127-636/26	04026575387434
127-636/35	04026575387571

Article REF	UDI - DI
127-710/17	04026575232154
127-710/26	04026575232161
127-710/35	04026575232178
127-711/17	04026575232291
127-711/26	04026575232307
127-711/35	04026575232314
127-712/17	04026575232147
127-712/26	04026575024032
127-712/35	04026575024049
127-713/17	04026575232246
127-713/26	04026575024056
127-713/35	04026575024063
127-714/17	04026575232192
127-714/26	04026575024070
127-714/35	04026575024087
127-715/17	04026575230150
127-715/26	04026575024094
127-715/35	04026575024100
127-716/17	04026575232208
127-716/26	04026575024117
127-716/35	04026575024124
127-717/17	04026575232253
127-717/26	04026575024131
127-717/35	04026575024148
127-718/17	04026575232215
127-718/26	04026575024155
127-718/35	04026575024162
127-719/17	04026575232260
127-719/26	04026575024179
127-719/35	04026575024186
127-720/17	04026575229628
127-720/26	04026575225422
127-720/35	04026575225439
127-721/17	04026575229697
127-721/26	04026575225507
127-721/35	04026575225514
127-722/17	04026575229635
127-722/26	04026575024193
127-722/35	04026575024209
127-723/17	04026575229703
127-723/26	04026575024216
127-723/35	04026575024223

Article REF	UDI - DI
127-724/17	04026575229642
127-724/26	04026575024230
127-724/35	04026575024247
127-725/17	04026575229710
127-725/26	04026575024254
127-725/35	04026575024261
127-726/17	04026575229659
127-726/26	04026575024278
127-726/35	04026575024285
127-727/17	04026575229727
127-727/26	04026575024292
127-727/35	04026575024308
127-728/17	04026575229666
127-728/26	04026575024315
127-728/35	04026575024322
127-729/17	04026575229734
127-729/26	04026575024339
127-729/35	04026575024346
127-730/17	04026575232239
127-730/26	04026575024353
127-730/35	04026575024360
127-731/17	04026575232284
127-731/26	04026575024377
127-731/35	04026575024384
127-732/17	04026575229680
127-732/26	04026575024391
127-732/35	04026575024407
127-733/17	04026575229758
127-733/26	04026575024414
127-733/35	04026575024421
127-736/17	04026575232222
127-736/26	04026575225408
127-736/35	04026575225415
127-737/17	04026575232277
127-737/26	04026575225460
127-737/35	04026575225477
127-738/17	04026575229673
127-738/26	04026575225446
127-738/35	04026575225453
127-739/17	04026575229741
127-739/26	04026575225484
127-739/35	04026575225491

SPII Model Lubinus, Hip Prosthesis Stem XL Neck, cemented

Article REF	UDI - DI
127-740/17	04026575241620
127-740/26	04026575241637
127-741/17	04026575241651
127-741/26	04026575241644
127-742/17	04026575241675
127-742/26	04026575241682
127-743/17	04026575241705
127-743/26	04026575241699

Article REF	UDI - DI
127-750/17	04026575241835
127-750/26	04026575241842
127-751/17	04026575241859
127-751/26	04026575242597
127-752/17	04026575241866
127-752/26	04026575241873
127-753/17	04026575241897
127-753/26	04026575241880

Article REF	UDI - DI
127-766/17	04026575241460
127-766/26	04026575241477
127-767/17	04026575241491
127-767/26	04026575241484
127-768/17	04026575241507
127-768/26	04026575241514
127-769/17	04026575241538
127-769/26	04026575241521

127-744/17	04026575241712	127-760/17	04026575241347	127-770/17	04026575241545
127-744/26	04026575241729	127-760/26	04026575241354	127-770/26	04026575241552
127-745/17	04026575241743	127-761/17	04026575241378	127-771/17	04026575241576
127-745/26	04026575241736	127-761/26	04026575241361	127-771/26	04026575241569
127-746/17	04026575241750	127-762/17	04026575241385	127-772/17	04026575241583
127-746/26	04026575241767	127-762/26	04026575241392	127-772/26	04026575241590
127-747/17	04026575241781	127-763/17	04026575241415	127-773/17	04026575241613
127-747/26	04026575241774	127-763/26	04026575241408	127-773/26	04026575241606
127-748/17	04026575241798	127-764/17	04026575241422		
127-748/26	04026575241804	127-764/26	04026575241439		
127-749/17	04026575241828	127-765/17	04026575241453		
127-749/26	04026575241811	127-765/26	04026575241446		

SPII Model Lubinus, Long Stem Prosthesis Standard Neck, cemented

Article REF	UDI - DI	Article REF	UDI - DI	Article REF	UDI - DI
127-910/26	04026575024872	127-918/26	04026575025114	127-926/26	04026575025350
127-910/35	04026575024889	127-918/35	04026575025121	127-926/35	04026575025367
127-911/26	04026575024902	127-919/26	04026575025145	127-927/26	04026575025381
127-911/35	04026575024919	127-919/35	04026575025152	127-927/35	04026575025398
127-912/26	04026575024933	127-920/26	04026575025176	127-928/26	04026575025411
127-912/35	04026575024940	127-920/35	04026575025183	127-928/35	04026575025428
127-913/26	04026575024964	127-921/26	04026575025206	127-929/26	04026575025442
127-913/35	04026575024971	127-921/35	04026575025213	127-929/35	04026575025459
127-914/26	04026575024995	127-922/26	04026575025237	127-930/26	04026575025473
127-914/35	04026575025008	127-922/35	04026575025244	127-930/35	04026575025480
127-915/26	04026575025022	127-923/26	04026575025268	127-931/26	04026575025503
127-915/35	04026575025039	127-923/35	04026575025275	127-931/35	04026575025510
127-916/26	04026575025053	127-924/26	04026575025299	127-932/26	04026575025534
127-916/35	04026575025060	127-924/35	04026575025305	127-932/35	04026575025541
127-917/26	04026575025084	127-925/26	04026575025329	127-933/26	04026575025565
127-917/35	04026575025091	127-925/35	04026575025336	127-933/35	04026575025572

SPII Model Lubinus, Long Stem Prosthesis XL Neck, cemented

Article REF	UDI - DI	Article REF	UDI - DI	Article REF	UDI - DI
127-940/26	04026575335572	127-948/26	04026575335732	127-956/26	04026575335893
127-940/35	04026575335589	127-948/35	04026575335749	127-956/35	04026575335909
127-941/26	04026575335596	127-949/26	04026575335756	127-957/26	04026575335916
127-941/35	04026575335602	127-949/35	04026575335763	127-957/35	04026575335923
127-942/26	04026575335619	127-950/26	04026575335770	127-958/26	04026575335930
127-942/35	04026575335626	127-950/35	04026575335787	127-958/35	04026575335947
127-943/26	04026575335633	127-951/26	04026575335794	127-959/26	04026575335954
127-943/35	04026575335640	127-951/35	04026575335800	127-959/35	04026575335961
127-944/26	04026575335657	127-952/26	04026575335817	127-960/26	04026575335978
127-944/35	04026575335664	127-952/35	04026575335824	127-960/35	04026575335985
127-945/26	04026575335671	127-953/26	04026575335831	127-961/26	04026575335992
127-945/35	04026575335688	127-953/35	04026575335848	127-961/35	04026575336005
127-946/26	04026575335695	127-954/26	04026575335855	127-962/26	04026575336012
127-946/35	04026575335701	127-954/35	04026575335862	127-962/35	04026575336029
127-947/26	04026575335718	127-955/26	04026575335879	127-963/26	04026575336036
127-947/35	04026575335725	127-955/35	04026575335886	127-963/35	04026575336043

SPII Model Lubinus, Long Stem Prosthesis Standard Neck, cemented

Article REF	UDI - DI	Article REF	UDI - DI	Article REF	UDI - DI
99-0005/72	04026575407187	99-0005/96	04026575407224	99-0017/24	04026575407323
99-0005/73	04026575407194	99-0005/97	04026575407231	99-0017/25	04026575407330
99-0005/74	04026575407200	99-0005/98	04026575407248	99-0017/26	04026575407347
99-0005/75	04026575407217	99-0005/99	04026575407255	99-0017/27	04026575407354
99-0005/76	04026575433506	99-0017/20	04026575407286	99-0017/28	04026575407361
99-0005/77	04026575433513	99-0017/21	04026575407293	99-0017/29	04026575407378
99-0005/78	04026575433520	99-0017/22	04026575407309	99-0017/30	04026575407385
99-0005/79	04026575433537	99-0017/23	04026575407316	99-0017/31	04026575407392

SPII Model Lubinus, Hip Prosthesis Stem Polished Neck, cemented

Article REF	UDI - DI	Article REF	UDI - DI	Article REF	UDI - DI
99-2720/17	04026575409877	99-2724/17	04026575409952	99-2728/17	04026575410033
99-2720/26	04026575409884	99-2724/26	04026575409969	99-2728/26	04026575410040
99-2721/17	04026575409891	99-2725/17	04026575409976	99-2729/17	04026575410057
99-2721/26	04026575409907	99-2725/26	04026575409983	99-2729/26	04026575410064
99-2722/17	04026575409914	99-2726/17	04026575409990	99-2738/17	04026575410071
99-2722/26	04026575409921	99-2726/26	04026575410002	99-2738/26	04026575410088
99-2723/17	04026575409938	99-2727/17	04026575410019	99-2739/17	04026575410095
99-2723/26	04026575409945	99-2727/26	04026575410026	99-2739/26	04026575410101

SPII Model Lubinus, Hip Prosthesis Stem XL Polished Neck, cemented

Article REF	UDI - DI
99-2760/17	04026575410118
99-2760/26	04026575410125
99-2761/17	04026575410132
99-2761/26	04026575410149
99-2762/17	04026575410156
99-2762/26	04026575410163
99-2763/17	04026575410170
99-2763/26	04026575410187

Article REF	UDI - DI
99-2764/17	04026575410194
99-2764/26	04026575410200
99-2765/17	04026575410217
99-2765/26	04026575410224
99-2766/17	04026575410231
99-2766/26	04026575410248
99-2767/17	04026575410255
99-2767/26	04026575410262

Article REF	UDI - DI
99-2768/17	04026575410279
99-2768/26	04026575410286
99-2769/17	04026575410293
99-2769/26	04026575410309
99-2770/17	04026575410316
99-2770/26	04026575410323
99-2771/17	04026575410330
99-2771/26	04026575410347

1.4 Primary clinical purpose of device*:

The non-active, surgically-invasive implantable SPII Model Lubinus Hip Stems manufactured by Waldemar Link GmbH & Co. KG are intended for long-term replacement of the femoral side of a diseased and / or defective hip joint in the human body. The SPII Model Lubinus Hip Stems form a hemiarthroplasty of the hip joint when combined with trauma heads (e.g. modular trauma heads or large heads) and form a total replacement of the hip joint if combined with prosthesis heads and an acetabular cup. The SPII Model Lubinus Hip Stems can be used with full-grown, anesthetized patients of any ethnic origin and sex. The SPII Model Lubinus Hip Stems are implanted with 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.
The SPII Model Lubinus Long Stem Prosthesis is dedicated mainly to revision hip arthroplasty.

1.5 Article REF(s)*:

See 1.3

1.6 Software version:

N/A

1.7 Affected serial or lot REF range:

This advisory notice applies to all listed article REFs with a production date after 01.02.2019 until the new label layout is launched with upcoming MDR certification.
Labels under MDR certification will have adapted Header:
“Size” is adapted to “Stem width”
“Type” is adapted to “Neck Type”

1.8 Associated devices:

N/A

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem*:

Due to two complaints it has come to our attention, that the SPII Model Lubinus label may be misinterpreted during surgery.
Particularly the specification “Size” (e.g. Figure 1: “x-large R4”) and “Type” (e.g. Figure 1: “Standard”) were mixed. As a result, the “Size” x-large R4 was interpreted as the head-neck-length.
With this advisory notice, we would like to draw your attention to the correct reading of the labels, see Figure 1 on page 1.

2.2 Hazard giving rise to the FSCA*:

A misinterpretation of the size and the type during surgery may lead either to the implantation of a different component than intended, or to a modified or prolonged surgery. If a different component was implanted than intended, the head-neck-length / offset may not correspond to the planned surgery outcome. In the worst case, intraoperative revision of the stem and replacement with another stem is the result.

2.3 Probability of problem arising:

The probability of a misinterpretation and implantation of a different component than intended is unlikely.

2.4 Predicted risk to patient/users:

For patients who have already been treated, there is no risk, as the probability of occurrence is classified as unlikely, and the use of a different sized implant would have been noticed during surgery.
An unintended head-neck-length / offset may be corrected by combining a suitable prosthesis head which may still lead to an acceptable result.

2.5 Further information to help characterize the problem:

The surgical technique provides detailed information to the user to ensure a safe handling of the product.

2.6 Background on Issue:

Two complaints were received regarding this issue.

2.7 Other information relevant to FSCA:

An updated layout of the label will be published after receipt of MDR certification.
Therewith there may be a mix of label layouts during the phaseout of the current labels.

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: Take note of Advisory Notice and instructions on how to read the label
☐ None

- We would be grateful if you could return the reply to us in any event until the **01.03.2024** as documentation of the corrective action.

3.2 By when should the action be completed ?:

01.03.2024

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

☐ Yes , the following: ☒ No, see 2.4.

3.4 Is customer Reply Required ?* :

☒ Yes, until: 01.03.2024 ☐ No

3.5 Action being taken by the manufacturer

☐ Product Removal
☐ On-site device modification / inspection
☐ Software upgrade
☐ IFU or labelling change
☒ Other: Publishing the Advisory Notice and instructions on how to read the label
☐ None

3.6 By when should the action be completed ?

01.03.2024

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 ?

☐ appended to this FSN
☐ not appended to this FSN

4. General Information

4.1 FSN Type*:

☒ New ☐ Update

4.2 For updated FSN

Reference REF 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:

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:

Persoonsgegevens

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.