

Date: 30.01.2025

Urgent Field Safety Notice **KNEE SPACER WITH GENTAMICIN**

For Attention of*: Physician, users, distributors, clients

Contact details of local representative (name, e-mail, telephone, address etc.)*

Synimed Synergie Ingénierie Médicale S.A.R.L.

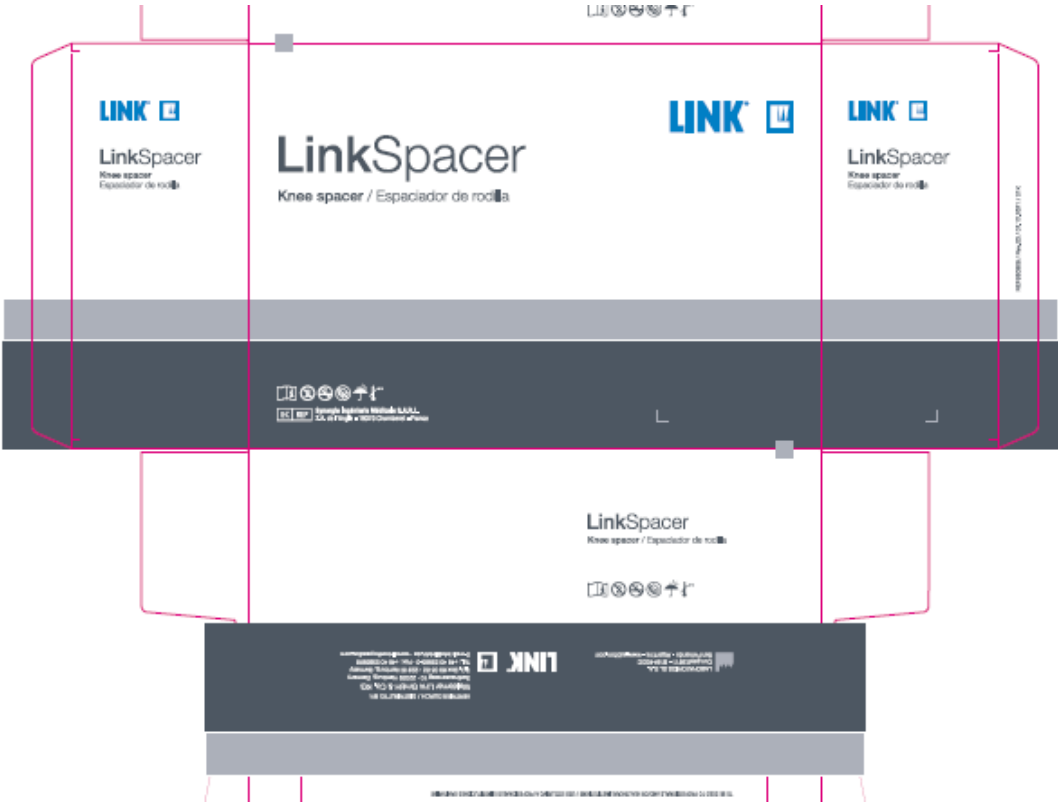
[Redacted]

[Redacted]

[Redacted]

SRN Authorized representative: FR-AR-000001802

Urgent Field Safety Notice (FSN)
LINK Spacer Knee
MISLABELING

1. Information on Affected Devices*	
1	<p>1. Device Type(s)*</p> <p>Knee Spacer with Gentamicin. Link Spacer Knee RD58. Sterile product. The knee spacer with gentamicin consists of the tibial and femoral component.</p>  <p>The diagram shows the packaging and components of the LinkSpacer Knee spacer. At the top, there is a pink-outlined box containing three smaller boxes, each labeled 'LINK' and 'LinkSpacer Knee spacer / Espaciador de rodilla'. Below this is a large grey rectangular box representing the main packaging, also labeled 'LinkSpacer Knee spacer / Espaciador de rodilla' and featuring a barcode and regulatory symbols. At the bottom, there is a dark grey rectangular box representing the tibial component, labeled 'LINK' and 'LINK SPACER'. The femoral component is partially visible below the tibial component.</p>
1	2. Commercial name(s) Link Spacer Knee
1	3. Unique Device Identifier(s) (UDI-DI) 07798034465430
1	4. Primary clinical purpose of device(s)* The knee spacer with gentamicin is a temporary implant (maximum 180 days) whose main function is to maintain the joint space during two-stage revision arthroplasty and whose secondary function is to assist in the treatment of joints infected by germs sensitive to gentamicin
1	5. Device Model/Catalogue/part number(s)* REF: 884407 – RD58
1	6. Software version N/A
1	7. Affected serial or lot number range REF: 884407 - Batch: 44683

1	8. Associated devices
.	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	The product with reference 880470 has been mislabeled. Item 884407 is a RIGHT Knee Spacer. However, the label on the back packaging side is for the left spacer, while on the front one is the right (RD).
2	2. Hazard giving rise to the FSCA*
.	<p>The problem is only in one of the labels on the case, the rest of the labels that identify the model, batch, and expiration date are correct. The labels on the primary packaging that maintains sterility (tyvek) and on the product are also correct.</p> <p>1 It is highly probable (as has happened) that this error is detected before starting the surgery,</p> <p style="padding-left: 20px;">a. in the distributor's warehouse, since an uncertainty is generated (between right and left) between the difference of that external label and the identification or traceability data: reference and lot. In this case, it never reaches the hospital or health institution.</p> <p style="padding-left: 20px;">b. If this were detected in the hospital institution, before entering the surgery, the hazard that could be generated is a delay of the surgery and the need for a rescheduling.</p> <p>2 The least probable event is that the shipment from the distribution chain was made only with the external label, and the product data was not verified with the traceability data, and not before surgery.</p> <p>In this case, once in surgery:</p> <p style="padding-left: 20px;">a. the surgeon would find a right variant when he required a left one. The hazard that could originate the event occurred, would be due to a delay during surgery, where the patient is exposed to the operating room and its conditions for longer than scheduled, which could generate some type of contamination with another germ.</p> <p style="padding-left: 20px;">b. the surgeon does not identify that it is right and the danger is that he implants it in a left knee.</p>
2	3. Probability of problem arising
.	All products in the indicated lot may be affected.
2	4. Predicted risk to patient/users
.	<p>In the known cases, none of the patients were injured, so a serious incident or public health hazard is ruled out This is because the previously identified hazard 2.2 1.a has been generated.</p> <p>Of the identified hazards, only two involve the patient.</p> <p>Hazard 2.2-2.a may generate a risk of contamination of the patient with another germ, due to delays during surgery, leading to a longer exposure time for the patient in the operating room.</p> <p>Hazard 2.2-2.b The right and left spacers are variants of the symmetrical spacers, initially manufactured by Laboratorios SL S.A. The differences between both types of variants are minimal, since both are generated from the symmetrical variant. Proof of this is that only one test system (symmetrical) is offered for the placement of the product. The patient should not have any problems during treatment, given the purpose of use (maintaining joint functionality by saving space and as an auxiliary action to help control the infection), and the limitations in mobility during treatment of the infected joint.</p>
2	5. Further information to help characterise the problem
.	NA
2	6. Background on Issue
.	As an immediate mitigation measure, a review and verification of all units of the lot in stock is requested to confirm the error in the corresponding labeling. If any unit or several units of the reviewed product have the labeling error, they must be immediately identified as non-conforming product and segregated in a restricted access area until the results of the investigation and final

	actions are obtained. For further guidance, attached are images of the packaging corresponding to the impacted product and lot, with the correct labeling and the incorrect labeling.
2	7. Other information relevant to FSCA
.	NA

3. Type of Action to mitigate the risk*			
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p> <p>Identify device: if after review of the product it is confirmed that the product has an error in the labeling, it should be identified as non-conforming product.</p> <p>Quarantine Device: Once the medical device is identified, it should be segregated and stored in a restricted access area until the results of the investigation and final actions are obtained.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">2. By when should the action be completed?</td> <td style="text-align: center;">As soon as possible</td> </tr> </table>	2. By when should the action be completed?	As soon as possible
2. By when should the action be completed?	As soon as possible		
3.	<p>3. Particular considerations for: Implantable device</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>because the health or physical integrity of patients is not affected</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">Yes</td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes		
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>All affected products will be relabelled</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">6. By when should the action be completed?</td> <td style="text-align: center;">As soon as possible</td> </tr> </table>	6. By when should the action be completed?	As soon as possible
6. By when should the action be completed?	As soon as possible		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">7. Is the FSN required to be communicated to the patient /lay user?</td> <td style="text-align: center;">No</td> </tr> </table>	7. Is the FSN required to be communicated to the patient /lay user?	No
7. Is the FSN required to be communicated to the patient /lay user?	No		
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?		

--	--

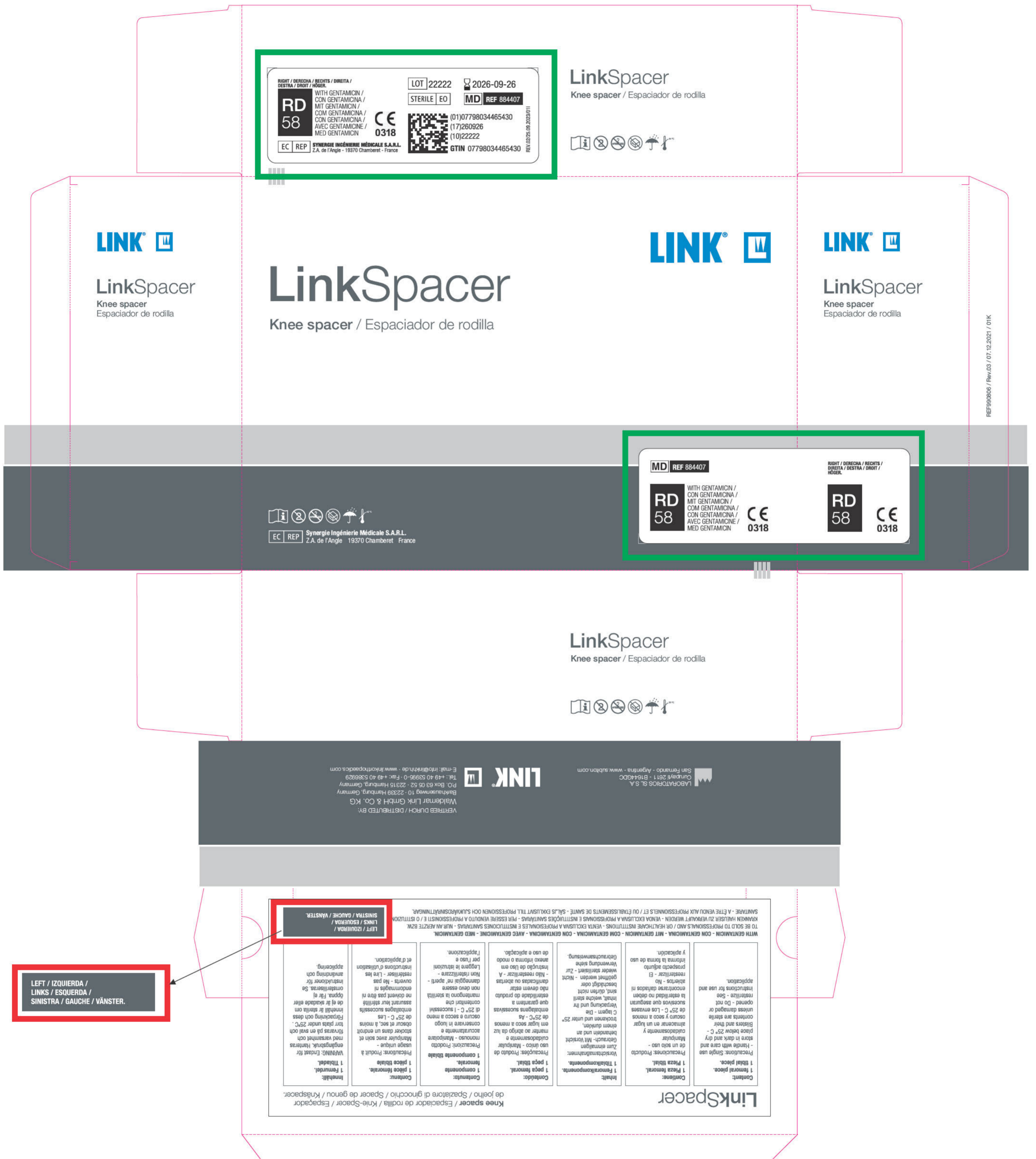
4. General Information*	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN NA
4.	3. For Updated FSN, key new information as follows: NA
4.	4. Further advice or information already expected in follow-up FSN? * No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: NA
4	6. Anticipated timescale for follow-up FSN NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Laboratorios SL S.A.
	b. Address [Redacted]
	c. Website address [Redacted]
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No. It is no necessary as the product is not commercialized in Argentina
4.	9. List of attachments/appendices: NA
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)

	<p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>
--	---

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Incorrect labeling



REF99806 / Rev.03 / 07.12.2021 / 01K