Customer Information
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Change of Packaging

Legal Manufacturer	**Waldemar Link GmbH & Co. KG** Barkhausenweg 10 22339 Hamburg GERMANY
Recipient	Distributors, customers and other responsible parties

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Statement of Confidentiality

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Content

1 Introduction

We would like to inform you about a change to our packaging systems that we will be implementing between August 2024 and March 2026. Due to the complexity of the change, we will roll it out in three phases. A detailed schedule can be found in chapter 4.

The adjustments build on each other and will therefore be implemented one after the other. The individual phases are as follows:

1. Adaptation of the carton sizes (secondary packaging) and adaptation of the outer film for all devices
2. Standardization of the sterile pouch specifications (primary packaging) for devices sterilized by irradiation
3. Extension of the shelf life from 5 years to 7 years for selected devices sterilized by irradiation

A list of the affected products can be found in chapter 2. Not every change applies to all LINK medical devices. Therefore, please check care-fully which change is relevant for the products you receive from us.

With this change we will improve our packaging system, ensure the availability of our sterile pouches and extend the life of our products. The division into three phases will allow us to use existing resources sustainably by using up almost all of the existing packaging materials.

This information letter is intended to inform you about the changes that will take place in phase 1 - the adjustment of carton sizes (secondary packaging) and outer film. We will inform you about the other phases in good time before they are implemented.

A more detailed description of the individual changes in phase 1 can be found in chapter 3.

2 Affected medical devices

LINK's medical devices remain unchanged. The change to the packaging system in phase 1 affects the secondary packaging of all LINK implants supplied sterile as well as their outer foil packaging, so that all sterile medical devices distributed by LINK are implicitly involved.

3 Description of the change

The change presented here is the result of a qualification project whose aim was to ensure the supply of sterile pouches. As part of the project, the packaging system was also revised and optimized. All necessary evidence of packaging validation in accordance with EN ISO 11607-1 and EN ISO 11607-2 has been provided.

Only the changes relevant to phase 1 are discussed below.

3.1 Changing the secondary packaging

In phase 1 of the packaging change, the secondary packaging (i.e. inner and outer cartons and any other inner protective packaging) is adapted to the new specifications. The dimensions of the inner and outer cartons of sterile packaged medical devices are changed while retaining the handling of the packaging and the visual appearance, e.g. the general carton imprint.

3.1.1 Changing the carton dimensions

Of the current ten variants of LINK product cartons (see Figure 1), three will be eliminated as part of this change, one variant will remain unchanged and the dimensions of the remaining six product cartons will be modified. The changes to the external dimensions (length, width, height) are maximum + 58 mm.

Figure 1: Product carton LINK

Figure 2 shows an example of the product carton with the largest dimensional changes in the length and width of the LINK portfolio.

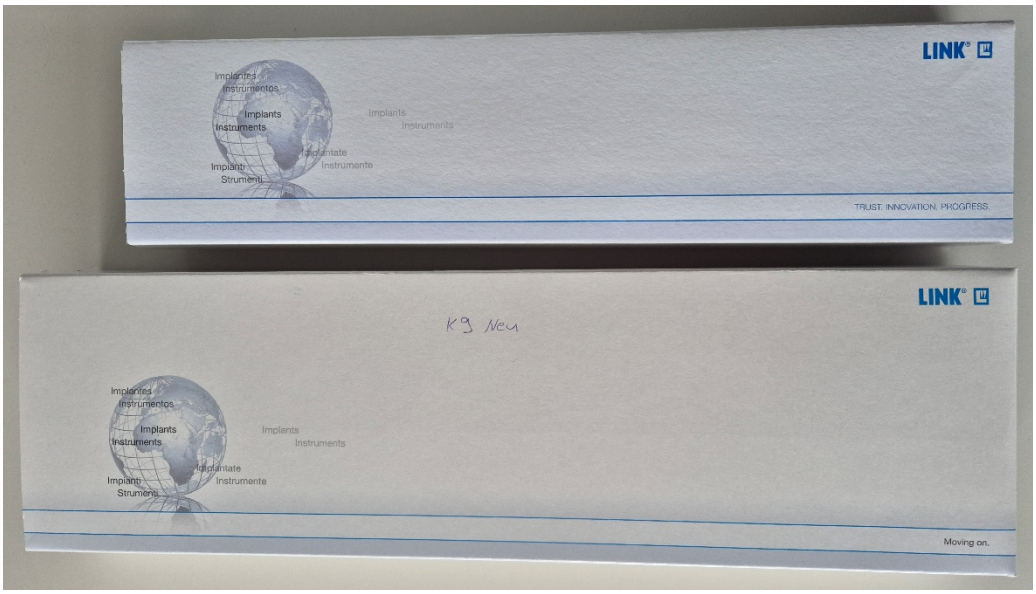
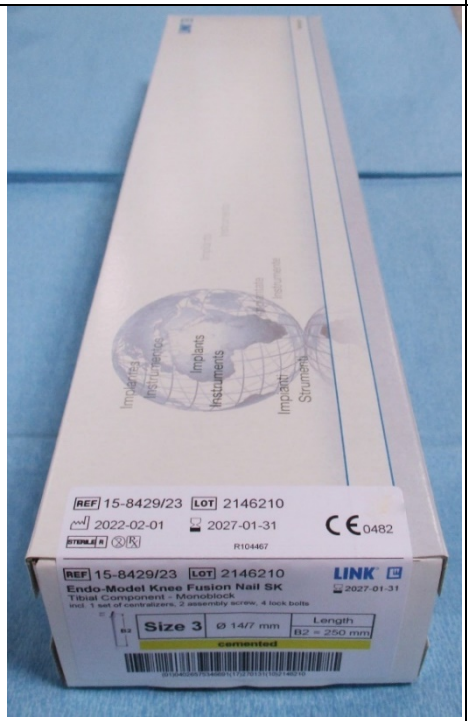


Figure 2: Top view of product carton K9 (bottom: new, top: old)

Table 1 lists all product cartons for sterile medical devices from LINK and defines the future changes. Furthermore, examples of the medical devices that are packaged in the respective product cartons are listed.

Table 1: Display of all LINK product cartons and the respective dimensional change

Internal description	**Product carton** (Image exemplary)	**Change phase 1**	**Representative LINK products**
K1		Length: 143 mm (+ 20 mm) Width: 70 mm (unchanged) Height: 50 mm (unchanged)	Small prosthesis heads, large screws
K2		Length: 185 mm (+ 2 mm) Width: 120 mm (unchanged) Height: 73 mm (+ 13 mm)	All acetabular cups made of UHMWPE, large prosthesis heads, femoral and tibial segments, plateaus
K4		Length: 507 mm (+ 58 mm) Width: 145 mm (+ 6 mm) Height: 102 mm (+ 1 mm)	Knee components
K7		Length: 305 mm (unchanged) Width: 143 mm (unchanged) Height: 95 mm (+ 20 mm)	Tibial components, femoral components, plateaus

Internal description	**Product carton** (Image exemplary)	**Change phase 1**	**Representative LINK products**
K8.1		Eliminated and replaced by K8.2.	Knee components, hip stems
K8.2		Length: 345 mm (unchanged) Width: 105 mm (unchanged) Height: 59 mm (+ 20 mm)	Knee stems, hip stems
K9		Length: 508 mm (+ 57 mm) Width: 149 mm (+ 43 mm) Height: 61 mm (unchanged)	Knee stems, hip stems

Internal description	**Product carton** (Image exemplary)	**Change phase 1**	**Representative LINK products**
FK6		Length: 153 mm (unchanged) Width: 93 mm (+ 15 mm) Height: 20 mm (unchanged)	Screws
FK7		Eliminated as this size is no longer required.	Screws
FK9		Eliminated as this size is no longer required.	Cerclage bands

3.1.2 Changing other protective packaging

If present, the dimensions of the previous inner protective packaging change analogously to those of the outer cartons. In two product cartons, not only the size of the inner protective packaging changes, but also the material. These deviating changes are shown in Table 2.

Table 2: Changing other protective packaging

Internal description	Graphical presentation of the change	Description of the change
K4	  	Instead of a cardboard inner box, an insert made of nap foam will be placed in the K4 in future. Another foam is placed on top of the implant. The final cardboard insert is turned.

Internal description	Graphical presentation of the change	Description of the change
K9		In the new version, additional foam is placed on top of the product. In addition, the cardboard insert will in future have side flaps and be inserted into the inner carton instead of being placed loosely as before.

3.1.3 Changing the film packaging

Instead of cellophane film with a tear strip, the product cartons will be packaged in shrink film without a tear strip from phase 1. A changeover is necessary as the cellophane wrapping machines will not be able to wrap the larger product cartons of the future. The use of a shrink film corresponds to the current state of the art and is also used by market competitors. The change is shown in Table 3.

Table 3: Comparison of film packaging

Secondary packaging with cellophane film (old)	Secondary packaging with shrink film (new)
	

4 Timeline for implementation

08/2024 - 02/2025
- Phase 1
- Adjustment of carton sizes
- Changeover as required, i.e. use up stock first
- New carton sizes + previous sterile pouch specification + 5-year shelf life

02/2025 - 08/2025
- Phase 2
- Standardization of the sterile pouche specification
- Changeover as required, i.e. use up stock first
- New carton sizes + new sterile pouch specification + 5-year shelf life

12/2025 - 03/2026
- Phase 3
- Extension of shelf life
- Changeover from a defined date
- New carton sizes + new sterile pouch specification + 7-year shelf life

Implementation of the change will begin in August 2024. All of the above-mentioned products will receive the new carton sizes from a production date of 02-2025 at the latest. In order to avoid having to dispose of packaging materials as far as possible, goods that were produced and stored before the changeover will not be repackaged. As a result, you may still receive products in the previous carton size and with cellophane wrapping after the start of the changeover. As soon as our stocks have been used up, the products will only be dispatched in the new carton sizes.

5 Measures

As the planned changes are an adaptation of the packaging system, the actual medical devices can be used just as safely as before. Please check whether the new carton sizes fit in your storage rooms and take any necessary measures (e.g. adjusting the shelf height).

6 Passing on the information and contacting LINK

Please ensure that all users of the above-mentioned products and other persons to be informed are aware of this packaging change. If you have supplied the products to third parties, please forward a copy of this information or inform us via info@link-ortho.com.

If you have any questions or problems, you can also contact info@link-ortho.com directly.

Poroshat Khalilpour
Director Quality Management