RÉPUBLIQUE LIBANAISE
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Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١/ ٢٥
رقم الصادر : ١٣/١/١٤٠٩٩
بيروت، في ٢٤ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Prostheses, joint, Knee, Tibial Component, Endo-Model SL Knee Prosthesis System Tilastan Proximal Tibial Spacers

الجهاز المعني بالمتابعة:

- Prostheses, joint, Knee, Tibial Component, Endo-Model SL Knee Prosthesis System Tilastan Proximal Tibial Spacers
- Trade Mark: Waldemar LINK GmbH & Co
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة

الذي يشير الى وجود خلل في طريقة تصنيع الصنف المذكور اعلاه ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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Datum

February 26, 2013

Sachbearbeiter

URGENT SAFETY INFORMATION FOR USERS

Affected products: **Augments – CombiCup R® System**

Item-no.

182-110/01
182-110/02
182-110/10
182-110/15
182-110/20
182-110/25

Dear Sir or Madam,

Our supplier has initiated this Field Safety Notice to the users/customers as a precautionary measure, in order to reduce the risk for future recurrence of such incidents.

There is the possibility of an early post-operative mobilization of the augments from the CombiCup R® acetabular cups. Such condition is the protrusion of one or more bone screws beyond the internal rim of the CombiCup R® cup before inserting the augment inside the cup.

As you were supplied with the affected products, please read carefully the information on the following pages and send us the reply fax back latest on March 15, 2013.

In conclusion, we apologize for any inconveniences caused and thank you for your understanding in this important matter.

Yours sincerely,
WALDEMAR LINK GmbH & Co. KG

[redacted]

Eingetragen im Handelsregister Hamburg, A Nr. 53 999 · USt.-ID Nr. DE 118451256
Pers. haft. Ges.: Interplanta GmbH, eingetragen im Handelsregister Hamburg, B Nr. 14 961 · Geschäftsführer der GmbH: Helmut D. Link, Norbert Ostwald
Deutsche Bank, Hamburg, Kto.-Nr. 33 122 0400, BLZ 200 700 00 · Postbank Hamburg 1047 66-204, BLZ 200 100 20

26. February 2013

LINK

Urgent Safety Information for Users

Augments of the CombiCup R® System

Item number (REF)	Material: Ti6Al4V			
	Angle°	Size	For insert	Lateralisation mm
182-110/01	0°	large	medium	0 (neutral)
182-110/02	0°	large	medium	+5
182-110/10	10°	large	medium	0 (neutral)
182-110/15	10°	large	medium	+5
182-110/20	20°	large	medium	0 (neutral)
182-110/25	20°	large	medium	+5

Problem description:

There is the possibility of an early post-operative mobilization of the augments from the CombiCup R® acetabular cups. **Such condition is the protrusion of one or more bone screws beyond the internal rim of the CombiCup R® cup before inserting the augment inside the cup.**

If the protrusion of at least one bone screw occurs during implantation of the augments, this may prevent the complete intra-operative conical coupling between augment and acetabular cup, increasing the risk of future mobilization of the augment.

Figure 1, below, shows the action of screwing of the bone screws when implanting the definitive CombiCup R® acetabular cup. The upper screw in the photo is correctly screwed, as it is not protruding inside the cup.

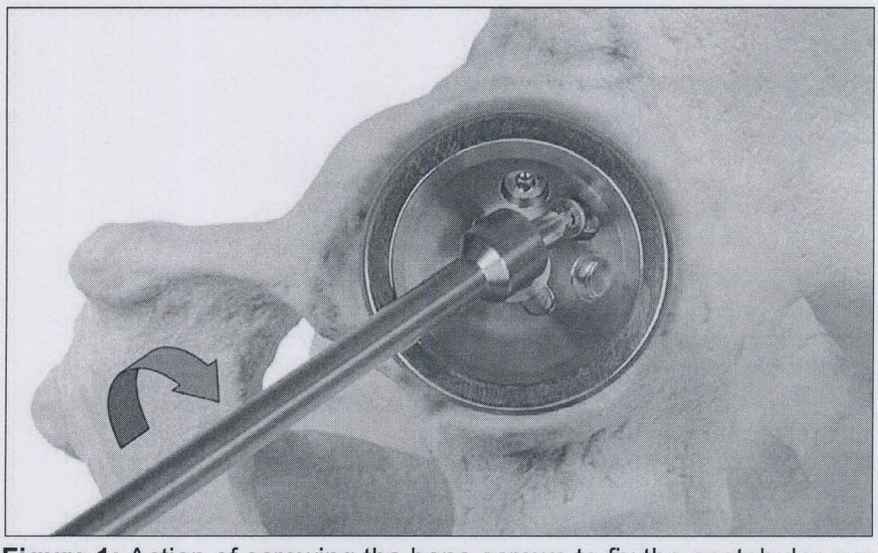

Figure 1: Action of screwing the bone screws to fix the acetabular cup

Figure 2, below, further shows the difference between a wrong final position of the bone screw after complete tightening into the cup (left photo, red rectangle), and the correct final position of the bone screw (right photo).

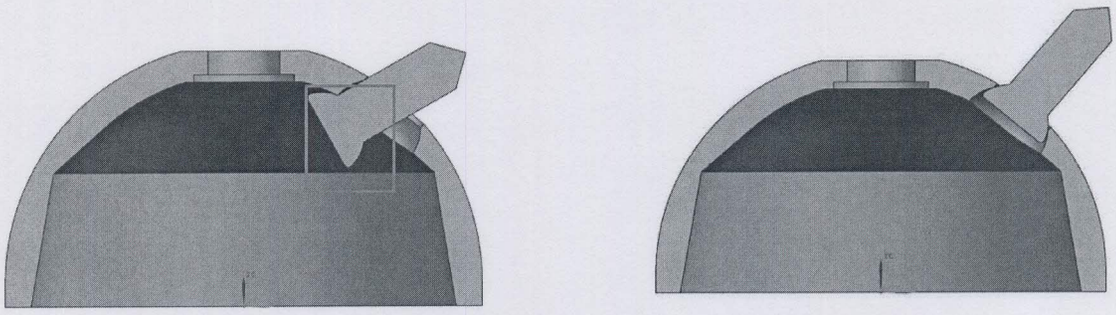

Figure 2: Wrong position (left) and correct position (right) of bone screw

Explanted bone screws, and the analysis on them always showed the presence of metal wear on at least one bone screw head, confirming that the screw head protruded beyond the internal rim of the cup, and became in direct contact with the dome of the augment (see figures 3 and 4, below).

Figure 3: Magnification of explanted bone screw head in case of CombiCup R® augment mobilization

The effect of such protrusion is proved by a polished circular strip on the dome of the CombiCup R® augment (see figure 4, below).

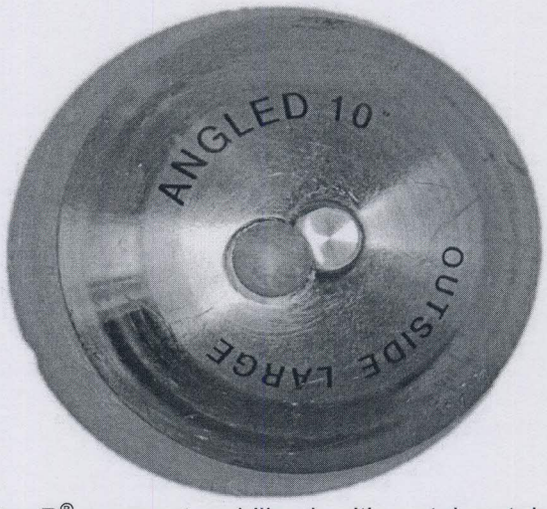

Figure 4: CombiCup R® augment mobilized, with metal-metal signs on the dome

Clinical consequences:
Our supplier supplier has initiated this Urgent Safety Information for Users as a precautionary measure, in order to reduce the risk for future recurrence of such incidents.

Corrective action:

- We kindly ask surgeons to pay particular attention when implanting CombiCup R® cups with augments. The intra-operative internal protrusion of bone screws must be absolutely avoided, in order to guarantee a complete conical coupling between the augment and the acetabular cup. Additionally, only for the augments provided with the polar safety screw (figure 5, below), the safety screw must be tightly screwed after inserting the augment into the cup, in order to stabilize the coupling.

Figure 4: Magnification of polar safety screw provided with the CombiCup R® augment

- LINK® is also updating the Surgical Technique provided with the CombiCup R® acetabular System, by introducing a note which advises of the possible incomplete coupling between augment and acetabular cup in case that a bone screw protrudes beyond the internal rim of the CombiCup R® cup intra-operatively.

Immediate measures:

- Products affected by this safety information are listed as item numbers (REF) on page 1 of this document.
- We kindly ask you to fill out the fax reply form to document that you received the Field Safety Notice **until March 15, 2013**.
- Please ensure that all users of the above products within your organization and other relevant persons have been notified of this **safety information**. If you have transferred the products to third parties, please pass on a copy of this information or notify the contact person indicated below.
- The official authorities have been notified of this Field Safety Notice.

Contact persons at Waldemar Link GmbH & Co. KG:
Customer Service, +49 40 5 39 95 – 330

[redacted]

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