19.08.2013

Urgent Notice on Safe Use of a Product

Metal-backed Tibial Plateau Endo-Model® 7 mm – Unicondylar Sled Prosthesis LINK®

REF / Item no.	Height (H) mm
Material: CoCrMo, UHMWPE	
15-2030/01	7
15-2030/05	7
15-2030/09	7

Figure 1: Endo-Modell® Metal-baked Tibia Plateau

The metal-backed tibia plateau consists of a UHMWPE plateau and a CoCr metal plate. As shown in figure 1 the total height is 7 mm.

Problem description:

During market surveillance of the product LINK® Unicondylar Sled Prosthesis - Metal-backed Tibial Plateau Endo-Model® 7 mm we received complaints about the wear of the UHMWPE-Plateau.
To ensure the best possible surgical results, we will phase out the metal-backed tibial plateau Endo-Model® 7 mm.

Clinical consequences:

The consequence of wear of the UHMWPE Plateau is a revision surgery of the implant.

Corrective action:

- The pre-operative planning and use of the metal-backed plateau 7 mm should be carried out according to our surgical technique and instructions for use.
- LINK® encourages customers to alternatively consider using the 7 mm all-poly tibia plateau.
- In case you do decide to use the 7 mm all-poly version, please contact your sales representative or our customer service as this may also require additional instruments.

Immediate action:

- All affected item numbers of this Urgent Notice on Safe Use are listed on page 1.
- Please confirm within 10 days the receipt of this Urgent Notice on Safe Use.
- Please ensure in your organization that all users and other relevant persons are aware of this Urgent Notice on Safe Use of a Product. If you have delivered the products to third parties, please forward a copy of this information or contact one of the below mentioned contacts.
- The responsible Competent Authority has been notified of this action and has received a copy of the safety information.

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