

Template QM 007	ORTHODYNAMICS
Field Safety Notice	Rev.: 000 – QM 12-20
	Datum/Date: 13.08.2012

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## URGENT FIELD SAFETY NOTICE

**Affected devices:**

**Product name:** Tibiagelenkteil, Pol-Endo – size small and medium  
Femurgelenkteil, Pol-Endo – size small

**Article numbers:** 23092000, 23815040, 23812000, 23815010 (tibia small)  
23093000, 23815050, 23813000, 23815020 (tibia medium)  
22012000, 22022000, 22512000, 22522000 (femur small)

**LOT numbers:** All

**Type of action:** Additional warnings relating to protected weight bearing in heavy patients

**Date:** 15<sup>th</sup> August 2014

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**Originator:**

Orthodynamics GmbH, Grapengießerstraße 34, 23556 Lübeck

**Attention:**

All users of Orthodynamics "MC" Pol-Endoprothese

**Description of the problem:**

Following a review of received reports of implant revisions Orthodynamics is issuing this voluntary FSN. The review identified a trend where premature revision is required in high body weight patients. Previous user information contraindicated patients with a BMI of 35kg/m<sup>2</sup> or above.

This FSN is to advise that Surgeons must read and follow the warnings regarding patients with a BMI of 35kg/m<sup>2</sup> or above. In addition it has been identified that patients above 90kg though not obese have had to have early revisions.


This FSN has supplementary warning to ensure protective measures are taken when using the smaller components of the range for patients with a weight above 90kg.

**Possible risks:**

The risk of revision due to instability and/or fracture of the components remains low. However, it has been identified that there is an increased risk of premature revision of the identified components in obese or high weight patients. To minimize this risk, Orthodynamics has provided the additional warning for all patients above 90kg, irrespective of obesity levels.

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**Actions to be taken by the user:**

The updated user information is available on the Orthodynamics website with the additional warning included on page 11. This information should be downloaded from the below address:

<http://www.orthodynamics.de/range/knie-endoprothetik/>

Orthopaedic surgeons should insert an implant of an appropriate size to the patient, using the largest implant available. For patients above 90kg that require a small or medium implant, the surgeon must warn them of the risk of premature failure and revision surgery should the guidelines of protected weight bearing not be followed.

Should you require any further information, please contact the person below.

**Forwarding of this Urgent Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organization.

**Contact person:**

Steven Meakins  
Safety Officer for Medical Devices  
Orthodynamics GmbH  
Phone: 0451/89000-0  
E-Mail: [Steven.Meakins@orthodynamics.de](mailto:Steven.Meakins@orthodynamics.de)

The undersigned confirms that the Bundesinstitut für Arzneimittel und Medizinprodukte has received a copy of this Urgent Field Safety Notice.

Kind regards

Orthodynamics GmbH

Steven Meakins  
SAFETY OFFICER FOR MEDICAL DEVICES

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